GLOBAL MEDI-CAL DRUG USE REVIEW (DUR) BOARD MEETING AGENDA

State of California
DEPARTMENT OF HEALTH CARE SERVICES

Notice is hereby given that the **Global Medi-Cal DUR Board** will conduct a public meeting on **Tuesday, February 26, 2019,** at the following location:

Department of Health Care Services
1700 K Street
1st Floor Conference Room
Sacramento, CA 95814
9:30 AM-3:00 PM
All times shown are approximate and are subject to change
Registration link to attend meeting via webinar

Report Type*	Agenda Item	Presenter	Time
C	**1.** Welcome/Introductions	Pauline Chan, RPh, MBA	930-940
I/D	**2.** Call to Order/Guidelines	Randall Stafford, MD, PhD	940-945
I/D	**3.** Meeting Logistics	Pauline Chan, RPh, MBA	945-950
R/A/D	**4.** Review and Approval of Previous Minutes from November 27, 2018	Randall Stafford, MD, PhD	950-955
	5. Old Business		
I/D	**a.** Review of Board Action Items from November 27, 2018	Pauline Chan, RPh, MBA	955-1000
I/D	**b.** Recommended Action Items for MCPs from November 27, 2018	Pauline Chan, RPh, MBA	1000-1005
R/A/D	**c.** FFS TAR Data: 4Q2018 (October – December 2018)	Paul Nguyen, PharmD, MBA	1005-1010
	6. New Business		
A/D	**a.** DUR Board Activities i. Annual Review: 2018 ii. Board Goals/Priorities 2019 iii. RetroDUR Review Proposal: Antihyperglycemic Medications	Andrew Wong, MD Randall Stafford, MD, PhD Robert Mowers, PharmD	1010-1030
Morning Break			1030-1040
R/D	**b.** Health Plan Presentation: Pharmacy Pay-for-Performance (P4P) Program	Doan Trang (Nina) T. Duong, PharmD [Clinical Pharmacist, IEHP]	1040-1120

R/A/D	**c.** DUR Annual Report to CMS i. FFY 2017: State Comparison Summary ii. FFY 2018: Fee-for-Service Draft Report iii. FFY 2018: Fee-for-Service Additional Data	Pauline Chan, RPh, MBA Hannah Orozco, PharmD Amanda Fingado, MPH	1120-1200
Lunch Break			1200-100
R/D	**d.** Recap of morning action items	Hannah Orozco, PharmD	100-110
R/A/D	**e.** Retrospective DUR i. Global Quarterly Report: 2Q2018 (April – June 2018) ii. FFS Quarterly Report: 4Q2018 (October – December 2018) iii. Biennial Report 2018: Part I	Amanda Fingado, MPH	110-150
R/A/D	**f.** Review of DUR Publications i. Alert (January 2019): Naloxone Legislation ii. Discussion/Recommendations for Future Bulletins	Shalini Lynch, PharmD	150-155
Afternoon Break			155-205
R/A/D	**g.** Prospective DUR: Fee-for-Service i. New GCNs for 4Q2018 (October – December 2018) ii. Therapeutic Duplication (TD) Alert: Update iii. Additive Toxicity (AT) Alert: Gabapentinoids **h.** DUR Educational Outreach to Providers: Fee-for-Service i. Outcomes: Additive Toxicity	Amanda Fingado, MPH	205-220
R/I//D	**i.** Pharmacy Update i. Improving Naloxone Access ii. CDC Opioid Guidelines Training Modules iii. 2019 Child Core Set iv. 2019 Adult Core Set v. CMS All State DUR Meeting vi. DUR Annual Report 2018 – Update and Timeline	Pauline Chan, RPh, MBA	220-245
R/D	**j.** Recap of afternon action items **k.** Looking ahead: Call for future meeting agenda topics i. May Presentation: Heidi Holtz, MD, MSEd [Anthem]	Hannah Orozco, PharmD	245-250
C	**7.** Public Comments **		250-300
I	**8.** Consent Agenda		
	a. Meeting feedback **b.** Next meeting: May 21, 2019 1700 K Street 1st Floor Conference Room Sacramento, CA 95814 **c.** Proposed DUR Board Meeting Dates for 2019: Tuesday, September 17, 2019 Tuesday, November 19, 2019		
	9. Adjournment		300

* REPORT TYPE LEGEND: **A: Action**; **C: Comment**; **D: Discussion**; **I: Information**; **R: Report**
** Comments from the public are always appreciated. However, comments will be limited to five minutes per individual.

Picture identification is required to gain access into the California Department of Health Services building. However, your security information will not be provided to the Global DUR Board.

You can obtain the Global DUR Board agenda from the Medi-Cal DUR Main Menu Web site (http://files.medi-cal.ca.gov/pubsdoco/dur/dur_home.asp).

GLOBAL MEDI-CAL DUR BOARD MEETING
PACKET SUMMARY
February 26, 2019

- **Suggested Sections to Review Prior to Meeting:**
  - Global DUR Board Goals/Priorities for 2019 (**Pages 26 – 27**)
    - Each year the Global Board establishes goals for the current year and beyond. The current Board chair is responsible for updating these slides each year. Review these slides in advance for discussion during the meeting.
  - FFY 2018 DUR Annual Report to CMS (**Pages 41 – 98**)
    - There is a lot of information provided in this packet, including a summary of the FFY 2017 annual report state-by-state comparison, as well as the first draft of the FFY 2018 DUR annual report to CMS. Reviewing the summary and the slides provided would be beneficial if there isn't time to review each document in detail.
  - Global Quarterly Report: 2Q2018 (**Pages 102 – 107**)
    - This is the first time pharmacy utilization data is being reported from claims processed through both the fee-for-service and managed care systems. Review this report in advance of the meeting and be prepared with questions and comments.
- **Important Reminders**
  - The following tentative dates for the 2019 DUR Board meetings have posted:
    - Tuesday, May 21, 2019
    - Tuesday, September 17, 2019
    - Tuesday, November 19, 2019

Global Medi-Cal DUR Board General Meeting Guidelines

- Be familiar with the Bagley-Keene Open Meeting Act
- Be familiar with Robert's Rules of Order
- Be courteous, respectful, and open minded of other's comments
- Be prepared by reviewing materials and downloading documents on PC/tablet in advance

Global Medi-Cal DUR Board Meeting Logistics

Pauline Chan, RPh, MBA

Logistics Summary

- Wi-Fi
- Seating Arrangement
- MCP Roll Call
- Making Comments
- Feedback Survey
- Housekeeping

Using Wi-Fi

- Wi-Fi is available during the Board Meeting
- A temporary passcode is announced and posted in the meeting room as soon as it is made available
- Direct further questions to the meeting organizer or DUR pharmacist

Seating Arrangement

- Assigned seats at main tables are for:
  - Board Chair and Board Members
  - DUR Team (DHCS/Conduent/UCSF)
  - Health Plan Representatives *with* RSVP
  - Presenters
- Reserved area (to the right of the main tables):
  - Health Plan Representatives *without* RSVP
  - Additional DHCS/Conduent/UCSF employees
- Unassigned (area behind main tables):
  - All other attendees

Roll Call

- After introduction around the room, a roll call to recognize Medi-Cal managed care health plans' participation will take place
- Roll call by alphabetical order of health plans
- Include those on the webinar
  - Health plan representatives should type in their health plan in the chat box at the beginning of the meeting so they can be recognized
  - Names of webinar attendees and their plans will be read aloud by webinar moderator
- Attendance will be recorded in meeting minutes

Health Plan Rep Comments

- Health plan representatives are encouraged to ask questions and make comments/suggestions throughout the meeting
  - Webinar:
    - Type questions/comments in chat box. Follow instructions from webinar moderator.
  - In-person:
    - Raise hand. Wait for Board Chair to call. When speaking, please go to the podium or use hand-held microphone for optimal audio transmission.

Public Comments

- Inform DHCS with advanced written notice, via email or other written correspondence. Please include the comment topic.
- Time allotted: 5 minutes
  - The Board Chair may grant extension
  - Speak at the podium using microphone
- Written material may be given to Board Chair

Feedback Survey

- Due to low response rate, electronic surveys have been retired
- Hardcopies of the survey are provided
  - Copies for Board are placed at the round table (distinguished by "BOARD MEMBER" in top corner)
  - Copies for all other attendees are at the sign-in table
- Please leave completed surveys at sign-in table
- YOUR FEEDBACK IS IMPORTANT

Housekeeping

- Please leave the area neat before leaving
- Throw away all trash
- Leave name cards at round table or sign-in table

GLOBAL MEDI-CAL DRUG USE REVIEW (DUR) BOARD
MEETING MINUTES
Tuesday, November 27, 2018
9:30 a.m. – 3:00 p.m.

Location: Department of Health Care Services (DHCS)
1700 K Street, 1st Floor Conference Room
Sacramento, CA 95814

Topic	Discussion
1) WELCOME/ INTRODUCTIONS	• The Global Medi-Cal Drug Use Review Board (the "Board") members and meeting attendees introduced themselves. • Board members present: Drs. Timothy Albertson, Chris Chan, Stan Leung, Johanna Liu, Janeen McBride, Robert Mowers, Yana Paulson, Randall Stafford, Marilyn Stebbins, Vic Walker, Andrew Wong, Iris Young, and Ramiro Zuniga. • Board members absent: Drs. Michael Blatt (attended the meeting via webinar), Lakshmi Dhanvanthari, and Jose Dryjanski. • DHCS staff present included Trudi Balestreri, MBA, Orlanda Bratlien, Pauline Chan, RPh, Marco Gonzales, PharmD, Raman Kaler, Paul Nguyen, PharmD, and Ivana Thompson, PharmD. Dorothy Uzoh, PharmD attended the meeting via webinar. • Representatives present from other Medi-Cal managed care plans (MCPs) attending in-person included Matthew Boga, MPH (Health Plan of San Joaquin), Matthew Garrett, PharmD (Health Plan of San Joaquin), Flora Siao, PharmD (California Health & Wellness), and Lynette Rey, PharmD (Partnership Health Plan of California). • Representatives present from other Medi-Cal managed care plans (MCPs) attending via webinar included Barrie Cheung, PharmD (Health Plan of San Mateo), An Dinh, PharmD (Inland Empire Health Plan), Kim Fillette, PharmD (Partnership Health Plan of California), Kris Gericke, PharmD (CalOptima), Lisa Ghotbi, PharmD (San Francisco Health Plan), Amit Khurana, PharmD (Aetna Better Health of California), Helen Lee, PharmD, MBA (Alameda Alliance for Health), Adam Horn, PharmD (CenCal Health), Ankit Shah, PharmD (UnitedHealthcare Community Plan of California, Inc.), Ming Shen, PharmD (Health Plan of San Mateo), and Mimosa Tran, PharmD (Molina Healthcare of California Partner Plan, Inc.).
2) CALL TO ORDER/ GUIDELINES	• The Chair of the Board, Dr. Andrew Wong, had notified DHCS and the Board that his flight was delayed and he would be arriving late. The Vice Chair, Dr. Randall Stafford, was absent as well, so the previous Chair, Dr. Robert Mowers, called the meeting to order. • Dr. Mowers stated that he is viewing a paper copy of the agenda and packet in order to follow the agenda and attachments being presented. He explained that any Board members using personal computing devices during the meeting are viewing the same materials provided to the public. This statement is required by Open Meeting rules. • Dr. Stafford, the Vice Chair, arrived and took over the meeting from Dr. Mowers. Dr. Stafford reviewed the general meeting guidelines and stated that everyone should have the mindset to be courteous, respectful, and open-minded.
3) PRESENTATION: REVIEW OF ROBERT'S RULES	Ms. Chan reviewed Robert's Rules of Order, including a detailed description of the main motion process. Moving forward, the Board agreed to more closely follow Robert's Rules of Order during Board meetings.

4) REVIEW AND APPROVAL OF PREVIOUS MINUTES FROM SEPTEMBER 18, 2018	The Board reviewed the minutes from the Board meeting held on September 18, 2018. Dr. Stebbins motioned that the minutes be approved. The motion was seconded. Ms. Chan pointed out one sentence in the minutes that she suggested be removed, as a result of discussions with Mr. Walker who said he had been misquoted. There was no further discussion. The Board voted to approve the minutes. **AYE:** Albertson, Chan, Leung, Liu, McBride, Paulson, Stafford, Stebbins, Walker, Young **NAY:** None **ABSTAIN:** Mowers **ABSENT:** Blatt, Dhanvanthari, Dryjanski, Wong After Dr. Wong arrived at the Board meeting, he stated he had a few minor edits to the minutes and motioned to approve the minutes to include his edits. The motion was seconded. There was no discussion. The Board voted to approve the minutes with Dr. Wong's edits. **AYE:** Albertson, Chan, Liu, McBride, Paulson, Stafford, Stebbins, Walker, Wong, Young **NAY:** None **ABSTAIN:** None **ABSENT:** Blatt, Dhanvanthari, Dryjanski, Leung, Mowers **ACTION ITEM**: Incorporate Ms. Chan and Dr. Wong's edits into the September 18, 2018 minutes and post to the DUR website.

5) OLD BUSINESS	**a.** Review of Board Action Items from September 18, 2018: i. General meeting guidelines – approved; will now be included in new Board member training and posted at the beginning of each Board meeting ii. Automatic refill – to be discussed today iii. New process: review of educational bulletins – approved; the Chair will designate board members to review each new bulletin iv. New process: changing existing bulletins – approved; any proposed changes will be brought to the Board for review v. DUR Board priorities – to be discussed today vi. Educational outreach: additive toxicity alert – letters to be mailed January 2019 **b.** Recommended Action Items for MCPs from September 18, 2018: Ms. Chan presented the recommended action items for MCPs from the Board meeting held on September 18, 2018. **c.** Automatic Refill: Dr. Stafford asked Mr. Walker if he would like to make a motion regarding auto-refill. Mr. Walker motioned to recommend to DHCS that they adopt an automatic refill policy similar to Medicare's and recommend pharmacies get consent to authorize auto-refill with the patient or patient's representative on an annual basis. Motion seconded. Dr. Paulson asked if the second part was also being recommended as part of the motion. Mr. Walker stated yes, it adds a specific timeframe. Dr. Liu questioned if this motion would apply only to new prescriptions. Mr. Walker said yes but authorization would be obtained annually. Dr. Young asked if once patients are enrolled and give consent, would this apply to all prescriptions or is this per patient per prescription. The Board also asked if this policy should apply only to chronic medications or just certain classes of medications, and should it exclude controlled substances. Dr. Leung pointed out that there is no language regarding pharmacist review of medications prior to automatic refill. He asked if the pharmacist should review the profile to determine medications appropriate for automatic refill. He also wondered if there was a requirement to document consent and how this would take place. Dr. Stafford requested an amended motion and Dr. Zuniga motioned that the Board recommend DHCS adopt a policy requiring pharmacies to conduct and document an annual review by the pharmacist of the patient's profile, in order to determine which medications should be approved for automatic refill. Further, all medications should be considered except for controlled substances. This motion was seconded. Mr. Walker stated that he

didn't think the Board needed to be that specific in the recommendation to DHCS. Dr. McBride noted that DHCS may not think of all the nuances involved and thought this discussion might be helpful. Ms. Chan stated that from DHCS' point of view, recommendations from the Board on how the final policy will be formulated are welcome and appreciated. She stated that DHCS feels the most important function of automatic refill is to improve medication adherence and clinical outcomes. Ms. Chan stated that any reasonable specific details or additional suggestions on the automatic refill policy would be taken into consideration by DHCS before there is a final decision on the policy.

Dr. Stafford suggested that the Board put forward a recommendation they agree is reasonable and provide their input to DHCS. Dr. Leung stated that the goals of automatic refill should balance adherence with waste and would like to emphasize that a pharmacist review of medication regimen would be important in order to determine what should or should not be automatically refilled. Dr. Stebbins stated that pharmacies could conduct outreach to assess the role of automatic refill for individual medications on the patient's profile. Dr. Paulson suggested changing the wording from:

- "Pharmacies may perform patient outreach to initiate refills in attempts to improve medication adherence and clinical outcomes" to:
- "Pharmacies must perform patient outreach to conduct medication review and initiate refills in attempts to improve medication adherence and clinical outcomes at the medication level"

Dr. Leung asked if documentation should be required. Dr. Liu stated that the Board of Pharmacy already requires a review of each medication. Dr. Zuniga suggested changing wording to "at least annually" instead of "annually" to account for more frequent review that may be necessary for more dangerous drugs. Dr. Blatt (via webinar) asked for clarification if the responsibility would be at the pharmacy level or the pharmacist level. Dr. Liu stated she would not support any policy that changed the recommendations from "pharmacies" to "pharmacists."

Dr. Mowers motioned to postpone the discussion on automatic refill to a time certain. Dr. Stebbins seconded the motion and then stated she thinks the Board should resolve this today and that it could be discussed this afternoon. Mr. Walker volunteered to work on this during lunch, in order to revisit the topic in the afternoon session and not postpone until the next meeting. Dr. Stafford called for a vote on the motion to postpone until a time certain. The motion was defeated.

AYE: Mowers
NAY: Albertson, Leung, Liu, McBride, Paulson, Stafford, Stebbins, Walker, Young
ABSTAIN: Chan
ABSENT: Blatt, Dhanvanthari, Dryjanski, Wong

Dr. Liu stated that it would be helpful to have the proposed language typed onscreen for the Board to review. Hannah Orozco, PharmD (Conduent) typed the edits to the screen, incorporating the Board's suggestions. Dr. Liu asked if there was any specific reason the Board would not just motion to follow Medicare policy on automatic refill. Dr. Stafford suggested she make a motion. Dr. Liu motioned that DHCS follow Medicare policy on automatic refills. The motion was seconded. There was no further discussion. The motion passed.

AYE: Chan, Leung, Liu, Paulson, Stebbins, Walker
NAY: McBride, Stafford, Young, Zuniga
ABSTAIN: Albertson, Mowers
ABSENT: Blatt, Dhanvanthari, Dryjanski, Wong

ACTION ITEM: The DUR Board recommendation that DHCS follow Medicare policy on automatic refills will be submitted to DHCS.

d. Global DUR Board Priorities: Dr. Stafford reviewed the Global Medi-Cal DUR Board

priorities and the questions for consideration of each priority. He asked if anyone on the Board has a motion relative to these priorities. Dr. Albertson noted the Board should consider education, policy, and containment or risk management/risk mitigation. He stated there was no need to act on each cluster in exactly the same way. Dr. Stafford asked if anyone would like to motion for further clarification. Dr. Zuniga wondered if the Board should prioritize topics, as all topics cannot be addressed at the same time and suggested listing the four topic clusters in order of preference. He motioned for the Board to rank the four priorities. Motion seconded.

Ms. Chan stated that she worked with Dr. Wong to put together the handout given to each Board member where the DUR priorities have been put into the vital directions framework. She stated that these priorities fit in with emerging issues and reviewed each of the topics. Dr. Stebbins stated that perhaps we shouldn't rank by category, as there may be overlap for the types of activities and some we are already doing. Amanda Fingado, MPH (UCSF) stated that the original iteration of these priority slides included an instruction to vote within each cluster and Dr. Wong took that part out of the final draft of the slides. She reminded the Board that the vote at the May meeting showed each topic cluster as important, with each topic cluster receiving either six or seven votes. Dr. Stafford called a vote on the motion to prioritize the topic clusters. The motion carried.

AYE: Chan, Leung, Paulson, Stafford, Walker, Young, Zuniga
NAY: Liu, McBride, Stebbins
ABSTAIN: Albertson, Mowers
ABSENT: Blatt, Dhanvanthari, Dryjanski, Wong

Dr. Stafford asked if there was a motion on how to prioritize the topics. Dr. Albertson motioned that each member should get one vote, with the topic cluster receiving the highest number of votes getting highest priority. Motion was seconded. Motion carried.

AYE: Albertson, Chan, Leung, Liu, McBride, Mowers, Paulson, Stafford, Stebbins, Walker, Young, Zuniga
NAY: None
ABSTAIN: None
ABSENT: Blatt, Dhanvanthari, Dryjanski, Wong

Vote Tally: Which topic cluster should be the Board's top priority?

- Optimizing Drug Prescribing and Dispensing
  - 8 VOTES: Chan, Leung, McBride, Mowers, Paulson, Stebbins, Walker, Young
- Optimizing Pain Management and Opioids
  - 0 VOTES
- Optimizing Chronic Disease Management:
  - 2 VOTES: Liu, Stafford
- Optimizing Biologics, Specialty Drugs, and Cost-effective Care:
  - 2 VOTES: Albertson, Zuniga

Dr. Stebbins motioned to make the three subtopics listed under the "Optimizing Biologics, Specialty Drugs, and Cost-effective Care" topic cluster move to fall under the "Optimizing Drug Prescribing and Dispensing" topic cluster. Motion was seconded. Motion carried.

AYE: Albertson, Chan, Leung, Liu, McBride, Mowers, Paulson, Stebbins, Walker, Young, Zuniga
NAY: None
ABSTAIN: Stafford
ABSENT: Blatt, Dhanvanthari, Dryjanski, Wong

ACTION ITEM: The DUR Board recommendation to move the subtopics from "Optimizing Biologics, Specialty Drugs, and Cost-effective Care" to "Optimizing Drug Prescribing and Dispensing" will be submitted to DHCS.

Dr. McBride proposed that we just look at super utilizers within the "Optimizing Drug

	Prescribing and Dispensing" topic cluster. There was some discussion on how best to define this group. Dr. McBride suggested following the literature. Dr. Paulson stated she thought this was too complicated for the discussion level here. Dr. Albertson didn't understand how this would apply to different disease states. Dr. Stafford stated that the Board could define super utilizers to help focus each topic and suggested that there may need to be different definitions, depending on the situation. Dr. Stebbins pointed out that we have pharmacy claims data, and may not see super utilizers in the hospital setting. Ms. Fingado agreed that pharmacy data is the most robust, and stated that any evaluation that requires using diagnostic criteria will be limited by only having the top two diagnostic codes available. Dr. Stafford called a vote on the motion to prioritize development of the definition of super utilizer. The motion was defeated. **AYE:** McBride, **NAY:** Albertson, Chan, Leung, Liu, Mowers, Paulson, Stebbins, Walker, Young, Zuniga **ABSTAIN:** None **ABSENT:** Blatt, Dhanvanthari, Dryjanski, Wong Dr. Zuniga motioned to remove the subtopic "Alternative Medicine (Pain Management) as Covered Benefits: Acupuncture" from the topic cluster, as acupuncture is already a covered benefit. Motion seconded. The motion was defeated. **AYE:** Walker, Zuniga **NAY:** McBride, Paulson, Stafford **ABSTAIN:** Albertson, Chan, Leung, Liu, Mowers, Stebbins, Young **ABSENT:** Blatt, Dhanvanthari, Dryjanski, Wong

6) NEW BUSINESS	**a.** Global DUR Board Activities i. Vice Chair Election: Ms. Fingado stated the current DUR bylaws do not specify details of the election process, and that the Board could have input on how future elections are conducted. Ms. Fingado shared that Open Meeting Act requirements must be followed, however, so the election must be held during a public meeting and there can be no secret ballots. Dr. Paulson motioned that each Board member must declare their interest in being Vice Chair in order to be considered for the position. Motion seconded. Motion carried. **AYE:** Albertson, Chan, Leung, Liu, McBride, Mowers, Paulson, Stafford, Stebbins, Walker, Young, Zuniga **NAY:** None **ABSTAIN:** None **ABSENT:** Blatt, Dhanvanthari, Dryjanski, Wong Dr. Wong arrived and took over facilitating the meeting from Dr. Stafford. Ms. Chan welcomed Dr. Wong and thanked him for filling in as Board Chair over the last year. She stated that it was important that the Board elect the Vice Chair at this meeting, in order to begin 2019 with both a Chair and Vice Chair. Drs. Albertson, Liu, and Paulson declared interest in being Vice Chair. Candidates gave brief oral statements describing their reasons for seeking this position. Vote Tally: Who should be the next Vice Chair? • Dr. Albertson: 6 VOTES – Albertson, McBride, Mowers, Stebbins, Wong, Zuniga • Dr. Liu: 5 VOTES – Chan, Leung, Liu, Stafford, Walker • Dr. Paulson: 1 VOTE - Paulson Dr. Albertson was elected Vice Chair for 2019. Ms. Chan stated that the terms of the elected officers would begin each year on January 1 following the election.

ii. Discussion of Vice Chair Election Process
Dr. Zuniga motioned that for future elections, each interested candidate should submit a brief statement of why the candidate is seeking the position by August 1. This timeline would allow candidate statements to be included in the Board meeting packet for the third quarter meeting.

AYE: Albertson, Chan, Leung, Liu, McBride, Mowers, Paulson, Stafford, Stebbins, Walker, Wong, Young, Zuniga
NAY: None
ABSTAIN: None
ABSENT: Blatt, Dhanvanthari, Dryjanski

ACTION ITEM: The DUR Board recommendation to have candidates for the vice chair position submit a statement to DHCS by August 1 of the election year will be submitted to DHCS.

ACTION ITEM: The DUR Board recommendation to update the DUR bylaws to include a more detailed election process will be submitted to DHCS.

b. Presentation: Reimbursement Changes for Covered Outpatient Drugs for Fee-For-Service Medi-Cal Pharmacy Providers – Trudi Balestreri, MBA, PMP, a consultant within the Pharmacy Policy Branch at DHCS provided an overview of Medi-Cal fee-for-service pharmacy reimbursement methodology changes for covered outpatient drugs. She summarized a 2011 report from the Office of the Inspector General that found that the fundamentally flawed nature of average wholesale price (AWP) caused Medicaid to pay too much for drugs.

Ms. Balestreri described how the Centers for Medicare & Medicaid Services (CMS) developed the National Average Drug Acquisition Cost (NADAC) to be used for drug ingredient cost reimbursement. The NADAC replaces AWP-17% in the "lowest of" formula. When NADAC is not available, Wholesale Acquisition Cost (WAC)+0% will be used as the backup. She noted there is great variability by drug between NADAC and AWP-17% and that NADAC does not take into account any drug rebates. For professional dispensing fee reimbursement, the new methodology is two-tiered, and is based on total annual (Medi-Cal and non Medi-Cal) claim volume. Annual provider attestation is required, with a dispensing fee of $13.20/claim for < 90,000 prescriptions dispensed annually and a dispensing fee of $10.05/claim for those dispensing ≥ 90,000 prescriptions annually. California has not implemented these reimbursement changes yet.

An attendee asked if NADAC takes into account cost data for non-sterile and sterile compounds when determining pricing. Ms. Balestreri stated she did not know and would have to look into that issue more thoroughly.

c. Retrospective DUR
i. Review of Retrospective DUR Criteria: New Additions to the Medi-Cal List of Contract Drugs in FFY 2017
- Dr. Lynch reported that each month there are usually modifications made to the Medi-Cal List of Contract Drugs, including the addition of new drugs. A review of utilization patterns for these drugs is conducted each year in order to determine if there is a need for further evaluation of any of the drugs added to the Medi-Cal List of Contract Drugs during the 2017 Federal Fiscal Year. Dr. Lynch stated that during the Federal Fiscal Year 2017 (between 10/1/16 and 9/30/17), there were a total of 16 new prescription medications added to the Medi-Cal List of Contract Drugs. Utilization data (total number of paid claims and utilizing beneficiaries with at least one paid claim) were reviewed for each of these drugs during the period between 10/1/15 and 08/31/18 to allow at least 11 months of utilization data before and after the drug was added to the Medi-Cal List of Contract Drugs. Thirteen of the drugs had low utilization (< 20 utilizing beneficiaries during all of the months reviewed) and were not reported in detail. There were no comments or suggestions for additional evaluation.

ii. Review of Retrospective DUR Criteria: Hepatitis C Virus (HCV) Drugs

- Dr. Lynch reported that at the November 15, 2016, DUR Board meeting, the DUR Board recommended a review of HCV medication utilization on an annual basis, primarily to evaluate potential HCV reinfection and retreatment in the Medi-Cal FFS population. Dr. Lynch presented updated data regarding the utilization of HCV medications among continuously-eligible Medi-Cal FFS beneficiaries that are 18 years of age and older and who have chronic HCV infection (dates of service between September 1, 2017 and August 31, 2018).
- Dr. Lynch reviewed the July 2018 DHCS policy for the treatment of HCV infection. Ms. Fingado stated that because the policy was so new the decision was made to include only Medi-Cal fee-for-service beneficiaries for this report. Ms. Fingado stated that at subsequent reviews data from both fee-for-service and managed care plans would be presented.
- Dr. Lynch reported a 32% decrease in total utilizing beneficiaries with a paid claim for an HCV treatment medication since the previous evaluation. However, after the July 2018 policy change a slight increase was noted in new starts (29.5 in July and August 2018, in comparison to 22.4 new starts in the preceding 10 months).
- Dr. Lynch shared that a review of drug utilization over time showed an increase in beneficiaries with paid claims for glecaprevir/pibrentasvir, which was added to the Medi-Cal Fee-for-Service List of Contract Drugs on January 1, 2018. Of note, there were no claims for ombitasvir/paritaprevir/ritonavir/dasabuvir or simeprevir during FFY 2018.
- Dr. Lynch also reported that the review of medical claims data found that all beneficiaries with a paid claim for an HCV treatment medication had at least one HCV-RNA level, HCV genotype test, and comprehensive metabolic panel, which follows AASLD-IDSA recommended guidelines. Further, thus far, all beneficiaries have not exceeded treatment duration limits for their particular regimen and there has yet to be any observed evidence of HCV retreatment.
- Given that pharmacy and medical claims data continue to show use of these drugs follows updated clinical guidelines, Dr. Lynch suggested that further action should be limited to annual review of HCV medication use.
- Dr. Stebbins agreed, and suggested repeating this review again in one year. Dr. Ghotbi (via webinar) suggested looking at: 1) treatment rates and 2) monitoring and reviewing those that have completed treatment. There was also discussion about looking at adherence rates for specialty pharmacy, as prior research has shown more robust adherence in the specialty pharmacy setting. There was no further discussion.

iii. Quarterly Report: 3Q2018 (July – September 2018) – Ms. Fingado presented the Medi-Cal fee-for-service quarterly DUR report for the 3rd quarter of 2018, which includes both prospective and retrospective DUR data. This quarterly report contains fee-for-service pharmacy utilization data presented in aggregate, and then stratified by Medi-Cal FFS enrollees only and by Medi-Cal managed care plan (MCP) enrollees only. This report includes all carved-out drugs processed through the FFS program. Ms. Fingado also pointed out that each year in the Q3 report the annual utilization summary of drugs (by sourcing status) that will be included in the annual report is presented. In addition, for reference, the Q3 report contains the top 10 drugs in each source code category, by total utilizing beneficiaries. Ms. Fingado stated that source status is determined through National Drug Code (NDC) and across all three categories the top NDC codes by total utilizing beneficiaries in the Federal fiscal year 2017 (FFY 2018) were almost identical to the previous year (FFY 2017).

iv. Review of FFS Physician Administered Drugs (PADs): 2Q2018 (April – June 2018) – Ms. Fingado showed the Board a summary of paid claims for physician-administered drugs paid through the Medi-Cal FFS program with dates of services between April 1, 2018, and June 30, 2018. These data were presented in three tables: 1) the top 20 drugs by utilizing beneficiaries, 2) the top 20 drugs by total reimbursement paid, and 3) the top 20 drugs by reimbursement paid per utilizing beneficiary.

v. Discussion: DUR Data Reports – Ms. Fingado presented a summary of the current data report timeframe, which includes all template reports the board receives at each meeting and does not include ad-hoc analyses. Ms. Fingado stated that the Board seems to have different data reporting needs now due to the expansion of the Board to include managed care plan representatives and the ability to now access data through MIS/DSS. Ms. Fingado suggested replacing quarterly physician-administered drug reports with two annual reports: one FFS only, one with FFS and MCP data. In addition, she proposed the addition of an annual review of the entire Medi-Cal pharmacy claims data and an expanded annual FFS pharmacy utilization report that would include comparative data and data trends beyond what is required by CMS.

Dr. Walker suggested that reports that use NDC are not useful. Dr. Albertson agreed the NDC table is not as useful as the other tables at the drug level. Ms. Fingado stated she would revise this in future tables. Dr. Ghotbi (via webinar) stated it would be helpful to look at all Medi-Cal pharmacy utilization data on a quarterly basis even if it some of the data would be delayed. Ms. Fingado asked if the Board would be OK with a report two quarters delayed (at first). She stated this reporting timeline could be revised when more is known about the completeness of the data in that report. She stated she could present the Q2 2018 data at the next Board meeting in February.

A motion was made to accept the proposed recommendations on data reports, with the addition of a quarterly pharmacy utilization report for all of Medi-Cal. Motion was seconded. Motion carried.

AYE: Albertson, Chan, Liu, McBride, Paulson, Stafford, Stebbins, Walker, Wong, Young, Zuniga
NAY: None
ABSTAIN: None
ABSENT: Blatt, Dhanvanthari, Dryjanski, Leung, Mowers

ACTION ITEM: The DUR Board recommendation that the standard data reports provided at each DUR Board meeting will be modified from the current structure will be submitted to DHCS.

Dr. Chan said he would like to see more data regarding the drugs going through *Treatment Authorization Review* (TAR). He noted the annual report to CMS only asks for the top 10 drugs and he would like to see the top 30 drugs that go through the TAR system, including their outcomes. Ms. Fingado stated that she has no access to TAR data and the data from that table comes via an annual request to the TAR office. Dr. Thompson said she might be able to help out with an updated request looking at more drugs than just the top 10.

Dr. Ghotbi (via webinar) stated she was worried that we haven't maximized the data we currently have access to and doesn't want to complicate things by adding in request for new data.

Dr. Chan said he was most interested in the type of drugs going through the TAR system and their approval/denial rate. He would like to know how many of the approved TARs are for new drugs and also to identify trends for new drugs entering the market. Dr. Chan motioned to request adjudication data from the Treatment Authorization Request (TAR) office on the top 30 drugs by total number of applications. Motion was seconded. Motion carried.

AYE: Albertson, Chan, Liu, McBride, Paulson, Stafford, Stebbins, Walker, Wong, Young, Zuniga
NAY: None
ABSTAIN: None
ABSENT: Blatt, Dhanvanthari, Dryjanski, Leung, Mowers

ACTION ITEM: The DUR Board request for adjudication data from the Treatment Authorization Request (TAR) office on the top 30 drugs by total number of applications will be submitted to

DHCS.

d. Review of DUR Publications presented by Dr. Lynch

i. Alert (September 2018): CURES Requirements – Dr. Lynch let the Board know that the DUR educational alert entitled, "Alert: Mandatory Use of CURES 2.0 Begins October 2, 2018 published in September 2018.

ii. Bulletin (September 2018): Immunization Update – Dr. Lynch let the Board know that the DUR educational bulletin entitled, "2018 Immunization Updates: Flu, Tdap, HepB, Zoster, MMR, Adult Vaccines published in September 2018.

iii. Discussion/Recommendations for Future Educational Bulletins – The calendar for future DUR educational bulletins was reviewed. Dr. Lynch reported that an educational bulletin reviewing latent tuberculosis infection (LTBI), including updates to recommended treatment regimen, is in progress.

e. Prospective DUR: Fee-for-Service

i. Review of DUR Alerts for New GCNs in 3Q2018 (July – September 2018): At each Board meeting, a list of new GCN additions with prospective DUR alerts turned on other than DD, ER, and PG are provided to the Board for review. At this meeting, the Board reviewed the alert profiles of the following GCNs:

- GCN #078588: ARIPIPRAZOLE LAUROXIL,SUBMICR. – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- GCN #078660: BUTALBITAL/ACETAMINOPHEN – Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD)
- GCN #078617: CELECOXIB/CAPSAI/M-SAL/MENTHOL – High Dose (HD), Low Dose (LD)
- GCN #078957: CHLORPHENIRAMINE/PE/CODEINE – Additive Toxicity (AT), Drug-Age (PA)
- GCN #077819: DARUNAVIR/COB/EMTRI/TENOF ALAF – Ingredient Duplication (ID)
- GCNs #078611 and #078619: DICLOFEN SOD/CAPSAI/M-SAL/MENT – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- GCN #078630: DICLOFEN SODIUM – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- GCN #078775: DICLOFENAC/LIDOCAINE/TAPE – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- GCN #078822: DORAVIRINE/LAMIVU/TENOFOV DISO – Ingredient Duplication (ID)
- GCN #078644: GABAPENTIN – Drug Allergy (DA), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- GCN #078838: HYDROMORPHONE HCL IN WATER/PF – Additive Toxicity (AT)
- GCNs #078551 and #078549: HYDROMORPHONE HCL/PF – Additive Toxicity (AT)
- GCN #078616: IBUPROFEN/CAPSAI/M-SAL/MENTHOL– Drug Allergy (DA), High Dose (HD), Low Dose (LD)
- GCNs #078119, #078120, #078121, and #078122: METOPROLOL SUCCINATE – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), High Dose (HD), Low Dose (LD)
- GCN #078565: MIDAZOLAM/KETAMINE/ONDANSETRON – Additive Toxicity (AT)
- GCN #078811: MORPHINE SULFATE IN 0.9% NACL – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- GCN #078814: NIFEDIPINE, MICRONIZED – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), High Dose (HD), Low Dose (LD)
- GCNs #078604 and #078605: PIMAVANSERIN TARTRATE – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Additive Toxicity (AT), High Dose (HD), Low Dose (LD)
- GCN #078821: POTASSIUM CHLORIDE IN WATER – Drug-Disease (MC),

Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)

- GCNs #078740 and 078741: RISPERIDONE – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- GCNs #078895 and #078896 SOD,POT CHLOR/SOD CIT/RICE SYR – Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)

There were no questions or objections to these alert profile recommendations. There was no further discussion.

ii. Therapeutic Duplication (TD) Alert – Ms. Fingado summarized an issue discovered within the Medi-Cal prospective DUR system in which turning off the ingredient duplication (ID) alert for a drug will now trigger a therapeutic duplication (TD) alert, unless the TD alert is also turned off for a specific drug. This is due to the Duplicate Therapy Module™ combining ID and TD alerts into one single alert. The issue was discovered when investigating why there were so many TD alerts being generated for quetiapine. The ID alert for quetiapine had been turned off by the Board and so all the ID alerts that had been generated by two formulations of quetiapine were now triggering TD alerts instead. The same problem was observed with lithium, which had the ID alert turned off for all non-300 mg formulations. A fix is not available at this time, so the solution proposed was for:

- Quetiapine – turn ID alert back on for all formulations, so as to distinguish between true therapeutic duplication with other antipsychotic medications and not have it combined with two formulations of quetiapine.
- Lithium – since the TD alert for lithium does not currently have any other drugs, it can be turned off for non-300 mg formulations without issue.

There were no questions or objections to these alert profile recommendations. There was no further discussion.

f. DUR Educational Outreach to Providers: Fee-for-Service

i. Update: MEDD 2018 – Ms. Fingado provided an update to the morphine equivalent daily dose (MEDD) letter, which was a repeat of a mailing done in 2016. The letter had been approved and was ready to be mailed and then a review was done of the accompanying article and found that the MEDD bulletin from September 2015 needs to be significantly updated in order to give providers the best and most current information available. For example, all links to MEDD calculators and apps were broken, the pain guidelines have been revised, and the listed MEDD thresholds are now less than what is being reported from most agencies.

Ms. Fingado noted that the Board wanted to review any updates to existing articles and asked for a volunteer to review the final draft of the bulletin before it is submitted.

Dr. Albertson volunteered to review the updated bulletin. There was no further discussion.

g. Pharmacy Update presented by Pauline Chan

i. Prescription Drug Overdose Prevention Initiative – Ms. Chan described the statewide overarching strategy for the initiative, which includes safe prescribing, access to treatment, naloxone distribution, a public education campaign, and data informed and driven interventions. Ms. Chan stated that the goals of the initiative include increasing the number of active buprenorphine prescribers, increasing the number of naloxone claims, decreasing all-cause overdose mortality, reducing the concomitant use of benzodiazepines and opioids, and reducing opioid claims > 90 mg MEDD.

ii. Smart Care California – Ms. Chan summarized results from a survey conducted by Smart Care California, a public-private partnership working to promote safe, affordable

health care in California. The survey found that among Medi-Cal plans progress was made among all four priorities identified to curb the opioid epidemic. The four priority areas included:

1) Prevent new starts
2) Manage pain safely
3) Treat addiction
4) Stop deaths

The highest % with an action plan in place were:

- Co-prescribing of naloxone (75.0%)
- Buprenorphine waiver training (68.8%)
- Naloxone member education (62.5%)
- Implement quantity limits (50.0%)
- Primary care addiction treatment (43.8%)

iii. Naloxone – Ms. Chan shared naloxone resources that are available from the California State Board of Pharmacy, including a no-cost webinar that fulfills the training requirement for pharmacists to furnish naloxone to patients without a prescription and a revised training guide, "Opioid Safety: Focus on Furnishing Naloxone – A Guide for California Community Pharmacists."

iv. Drug Takeback Services – Ms. Chan reported that drug take backs are available for consumers to safely dispose unwanted or expired prescription drugs. Drug take back pharmacies are registered with the California State Board of Pharmacy and provide on-site collection bins and envelopes for mailing back medications.

v. Six Building Blocks – Ms. Chan shared materials from a collaboration between the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control & Prevention (CDC), and Washington State Department of Health that identifies six key work areas for redesigning and improving clinic management of patients who are on chronic opioid therapy. The Six Building Blocks are designed to provide a framework for a team-based approach to improving opioid management in primary care.

vi. Million Hearts 2022 – Ms. Chan provided a link to research reports provided by Million Hearts 2022, including a report on state-variation and news article. Million Hearts 2022 aims to achieve an 80% or greater performance of the ABCS (appropriate aspirin use, blood pressure control, cholesterol control, and smoking cessation) and at least a 20% reduction in physical inactivity, tobacco use, and sodium consumption.

vii. Medi-Cal at a Glance – Ms. Chan provided a link to the most recent Medi-Cal at a Glance report, which provides information on the Medi-Cal population, including delivery system, gender, age, aid categories, race/ethnicity, and primary language.

viii. CMS DUR Annual Report 2018 – Ms. Chan provided a link to CMS-R-153, which includes the final FFY 2018 annual report to CMS for managed care plans. As a reminder, the FFY 2018 report covers the period of 10/1/17 to 9/30/18 and the executive summary for each plan will be presented to the Global DUR Board in May 2019. The report is due to CMS on June 30, 2019.

Dr. Ghotbi (via webinar) asked if plans should be using the template on the CMS site or the one found via the CMS-R-153 link. Dr. Thompson stated that the contract managers for the managed care plans should have sent out a communication with a draft template in a .zip file on how to prepare for the annual report. Dr. Thompson said communication should have gone out to the plan contact, but if plan contacts have not heard anything, to please let Dr. Thompson know.

h. Recap of today's action items – Ms. Chan reported that today's action items for managed care health plans would be distributed as soon as possible.

	i. Looking ahead: Call for future meeting agenda – Ms. Chan requested future meeting agenda items to be shared with her on an ongoing basis.

7) PUBLIC COMMENTS	• Nathan Langley from Safer Lock reported that Assembly Bill 2859, which requires pharmacies to carry medication locking devices by 2019 to prevent opioid abuse, was approved by Governor Brown on August 28, 2018. Mr. Langley wanted to make sure the Board was aware that Safer Lock is a locking device that fulfills the legislative requirements of Assembly Bill 2859.
8) CONSENT AGENDA	• The next Board meeting will be held from 9:30 a.m. to 3:00 p.m. on February 26, 2019, in the DHCS 1st Floor Conference Room located at 1700 K Street, Sacramento, CA 95814.
9) ADJOURNMENT	• The meeting was adjourned at 2:58 p.m.

Action Items	**Ownership**
Incorporate Ms. Chan and Dr. Wong's edits into the September 18, 2018 minutes and post to the DUR website.	Amanda
The DUR Board recommendation that DHCS follow Medicare policy on automatic refills will be submitted to DHCS.	Pauline
The DUR Board recommendation to move the subtopics from "Optimizing Biologics, Specialty Drugs, and Cost-effective Care" to "Optimizing Drug Prescribing and Dispensing" will be submitted to DHCS.	Amanda
The DUR Board recommendation to update the DUR bylaws to include a more detailed election process will be submitted to DHCS.	Amanda/Pauline
The DUR Board recommendation to have candidates for the vice chair position submit a statement to DHCS by August 1 of the election year will be submitted to DHCS.	Amanda/Pauline
The DUR Board recommendation that the standard data reports provided at each DUR Board meeting will be modified from the current structure will be submitted to DHCS.	Amanda
The DUR Board request for adjudication data from the Treatment Authorization Request (TAR) office on the top 30 drugs by total number of applications will be submitted to DHCS.	Ivana

Board Action Items from November 27, 2018

- Update bylaws to include election process details
  - Election process approved, bylaws don't need modified at this time
- Candidates for Vice Chair to submit statement of interest to DHCS by August 1 (for September elections)
  - Approved, reminders to be sent to Board before deadline
- Update Board priorities to move three subtopics under "Optimizing Biologics, Specialty Drugs, and Cost-effective Care" to "Optimizing Drug Prescribing and Dispensing"
  - Approved, edits included in slides to be discussed today
- DHCS to follow Medicare policy on automatic refills
  - DHCS considering recommendation
- Updates to standard data reports for Board meetings
  - Approved, new reports to be presented today

GLOBAL MEDI-CAL DRUG USE REVIEW BOARD
November 27, 2018 BOARD MEETING MCP ACTIONS

MCP: _____

Name of DUR representative: _____Attended meeting? Yes ___ No ___

Summary of Required Actions

I. Educational Bulletins: MCP to have a process for distribution of provider education programs and materials developed by Global DUR Board to their providers via established mechanisms.

Required dissemination of DUR educational bulletins and alerts		
Description	**Mechanism of dissemination**	**Date of Dissemination**
September 2018 Bulletin: 2018 Immunization Updates: Flu, Tdap, HepB, Zoster, MMR, Adult Vaccines		
September 2018 Alert: Mandatory Use of CURES 2.0 Begins October 2, 2018		

Summary of Global Medi-Cal DUR Board Activities
(not required to document on the Annual Report to CMS)

1. MCPs are encouraged to review plan's automatic refill policy and cross walk with Medicare automatic refill policy.

2. When reviewing retrospective DUR review criteria, consider including new drugs added to the formulary within the last 12 months.

3. When reviewing retrospective DUR review criteria, consider including a review of hepatitis C virus (HCV) drug use, the treatment rates and those received completed treatment.

4. MCPs to review plan's top 30 prior authorization drugs, including the number of submissions, and categories of action taken (acceptance, denied or others), and develop a quality improvement plan as appropriate.

5. MCPs to review the results of a survey conducted by SMART CARE on progress made in the four priority areas to combat prescription drug overdose and prevention.

6. MCPs to develop a plan to complete CMS annual DUR report:
    a. Establish a timeline for review and completion by April 1, 2019.
    b. Use the DHCS' FAQ and companion guide for resources.
    c. Review CMS guidance on website.

Reminders

- MCPs are required to have a process for distribution of provider education programs and materials developed by Global Medi-Cal DUR Board to their providers.

- MCPs are encouraged to volunteer to present best practices at future board meetings.

- Future Global DUR Board Meeting Dates:

    - February 26, 2019
    - May 21, 2019
    - September 17, 2019
    - November 19, 2019

Medi-Cal Fee-for-Service TAR Report
4TH Quarter 2018
(October – December 2018)

Paul Nguyen, Pharm.D., MBA
February 26, 2019

Introduction

Reasons an approved *Treatment Authorization Request* (TAR) may be required include:

- Drugs not on the Medi-Cal fee-for-service Contract Drugs List (CDL)
- Code 1 restrictions for drugs used to treat conditions other than those specified on the CDL
- Pre-payment control exceptions to dispensing quantities, frequency of billing limitations, minimum contraceptives dispensing quantity, and maximum dispensing quantity
- Drug on CDL does not include all routes of administration
- Paid pharmacy claims exceed the six prescription monthly limit

Top 30 TAR Drugs - 1

Antipsychotics

- 66.1% of all TAR requests
- 11 of the top 32 TAR drugs
- TAR reasons:
  - Physician Administered Drugs
  - Non-CDL drugs
  - Code 1

Top 30 TAR Drugs - 2

Insulins

- 2.9% of all TAR requests
- Vials versus pens

Opioids

- 5.9% of all TAR requests
- Code 1
  - Maximum number of tablets per dispensing
  - Maximum number of dispensings over time
  - Drug formulation

Top 30 TAR Drugs - 3

Substance Use Disorder

- 4.3% of all TAR requests
- Code 1
  - Indication
  - Provider
  - Quantity
  - Frequency
- Pain management
  - Patches
  - Buccal film

Questions

QUARTERLY SUMMARY
FEE-FOR-SERVICE TREATMENT AUTHORIZATION REQUESTS
REPORT PERIOD: 4TH QUARTER 2018 (OCTOBER – DECEMBER 2018)

Rank	Drug Description	Route	Total TAR Submitted	Total TAR Approved
1	PALIPERIDONE	INJECTION	10,242	7,865 (77%)
		ORAL	2,003	1,401 (70%)
2	ARIPIPRAZOLE	ORAL	6,631	4,905 (74%)
		INJECTION	5,193	3,984 (77%)
3	RISPERIDONE	ORAL	5,918	4,699 (79%)
		INJECTION	793	650 (82%)
4	QUETIAPINE	ORAL	3,921	2,961 (76%)
5	HYDROCODONE/ACETAMINOPHEN	ORAL	2,651	2,140 (81%)
6	HALOPERIDOL	INJECTION	2,492	1,846 (74%)
		ORAL	401	322 (80%)
7	BREXPIPRAZOLE	ORAL	2,169	1,417 (65%)
8	INSULIN GLARGINE,HUM.REC.ANLOG	INJECTION	862	503 (58%)
	INSULIN LISPRO	INJECTION	521	280 (54%)
	INSULIN ASPART	INJECTION	220	106 (48%)
	ALL OTHER INSULIN PRODUCTS	INJECTION	450	225 (50%)
9	OLANZAPINE	ORAL	1,885	1,507 (80%)
		INJECTION	177	141 (80%)
10	METHYLPHENIDATE HCL	ORAL	1,813	1,214 (67%)
11	INFANT FORMULA	ORAL	1,562	1,241 (79%)
12	CARIPRAZINE HCL	ORAL	1,549	1,075 (69%)
13	BUPRENORPHINE HCL[1]	ORAL	770	560 (73%)
	BUPRENORPHINE HCL/NALOXONE HCL[1]	ORAL	389	313 (80%)
	BUPRENORPHINE[2]	INJECTION	94	70 (74%)
	BUPRENORPHINE[2]	PATCH	207	58 (28%)
	BUPRENORPHINE HCL[2]	ORAL	80	57 (71%)
14	NALTREXONE MICROSPHERES	INJECTION	1,472	1,192 (81%)
15	LITHIUM	ORAL	1,215	916 (75%)
16	LURASIDONE HCL	ORAL	1,147	864 (75%)
17	BENZTROPINE MESYLATE	ORAL	1,081	785 (73%)
18	COMPOUNDED DRUGS	VARIABLE	1,067	797 (75%)
19	LACTULOSE	ORAL	1,065	815 (77%)
20	TRAZODONE HCL	ORAL	1,060	806 (76%)
21	LORAZEPAM	ORAL	882	721 (82%)
		INJECTION	86	62 (72%)
22	OXYCODONE HCL	ORAL	965	777 (81%)
23	DEXTROAMPHETAMINE/AMPHETAMINE	ORAL	875	475 (54%)
24	BUPROPION HCL	ORAL	893	487 (55%)
25	GUANFACINE HCL	ORAL	742	542 (73%)
26	POLYETHYLENE GLYCOL 3350	ORAL	739	455 (62%)
27	ALBUTEROL	INHALER	686	465 (68%)
28	ATOMOXETINE HCL	ORAL	685	497 (73%)
29	GABAPENTIN	ORAL	648	454 (70%)
30	TACROLIMUS	ORAL	511	415 (81%)
		TOPICAL	70	41 (59%)
31	ZIPRASIDONE	ORAL	535	424 (79%)
		INJECTION	< 20	< 20 (92%)
32	MORPHINE SULFATE	ORAL	547	413 (76%)

[1] OPIOID WITHDRAWAL THERAPY AGENTS, OPIOID-TYPE
[2] OPIOID ANALGESICS

Global Medi-Cal
Drug Use Review Board
Annual Review 2018

Andrew Wong, MD, Board Chair
Pauline Chan, R.Ph., MBA
February 26, 2019

2018 Annual Review - 1

- Implemented the DUR requirements of Medicaid and CHIP Managed Care Final Rule (CMS-2390-F)
- Implemented the All Plan Letter 17-008 (DUR)
- Revised the Global DUR Bylaws

2018 Annual Review - 2

- Expanded the Board from seven members to sixteen members
  - New members from Medi-Cal managed care health plans
  - Revised board orientation manual and meeting guidelines
- Increased public access to meetings via webinar

2018 Annual Review - 3

- Conducted systematic review of prospective DUR alerts
- Conducted systematic review of retroactive DUR criteria
- Published six educational bulletins/alerts
- Aligned DUR board goals with DHCS Quality Strategy
  - Low dose aspirin study as part of DHCS Million Hearts initiative

2018 Annual Review - 4

- MCOs had opportunities to attend academic detailing training
  - Opioid Stewardship and Chronic Pain (primary care)
  - Opioid Safety: Focus on Furnishing Naloxone (community pharmacists)
- CMS annual reports (FFS and MCOs)
  - Established a timeline
  - Annual report companion guide & FAQs

2018 Annual Review - 5

- Successful transition from a Fee-for-Service DUR program to include managed care health plans
- Robust participation of health plans:
  - Presenting Best Practices and Demonstration Projects
  - Sharing of innovative ideas and lessons learned
  - Connecting and distributing DUR education bulletins
- Identified infrastructure needs and laid the groundwork for priority actions for 2019

Thank You

Global Medi-Cal Drug Utilization Review Board 2019 Goals and Priorities

Randall Stafford, MD, PhD
Pauline Chan, R.Ph., MBA
February 26, 2019

Global Medi-Cal DUR Board Goals 2019 - 1

- Advise DHCS regarding the revision of DUR reports to include drugs commonly used in both Medi-Cal Fee-for-Service (FFS) and Managed Care Organizations (MCOs)
- Promote dialogue, collaboration among MCOs
  - Present best practices and projects
  - Share innovative ideas and lessons learned
  - Update list of priority areas (topic clusters)
  - Disseminate DUR educational bulletins
  - Integrate/align FFS and MCO DUR action items

Global Medi-Cal DUR Board Goals 2019 - 2

- Align goals with DHCS Quality Strategy
  - Better health, better care, lower cost
- Advise DHCS in the implementation of Medicaid Drug Utilization and Review Minimum Standards for the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

Global Medi-Cal DUR Board Goals 2019 - 3

Priority Area Topic Clusters

- Optimizing Drug Prescribing and Dispensing, including **specialty** drugs
- Optimizing Pain Management and Opioids
- Optimizing Chronic Disease Management, including **prevention**

Bolded = instead of separate topics, specialty drugs and prevention were regrouped, included in top three

Optimizing Drug Prescribing and Dispensing, including **specialty** drugs

1. Appropriate Use of Medication in High Utilizers and Super Utilizers
2. Formulary Review: Prior Authorization Process Improvement
3. Medication Use Optimization: Reduce Polypharmacy and Eliminate Unnecessary Drugs
4. Strategies to Prevent Filling Prescriptions Already Cancelled
5. Fostering Closer Collaboration between Medical and Pharmacy Services for Optimal Care
6. **Specialty Drugs and Biosimilar Drugs**
7. **Specialty Pharmacy: Cost Effectiveness and Quality of Care**
8. **Biologics in Immunotherapy: (e.g., CAR T-Cell Therapy)**

Optimizing Pain Management and Opioids

1. Opioids and Benzodiazepine Combination Use
2. Alternative Medicine (Pain Management) as Covered Benefits: Acupuncture
3. Pain Management Guidelines

Optimizing Chronic Disease Management, including **prevention**

1. Diabetes Management
2. Hypertension Management
3. Optimal Drug Use: Population Health and Chronic Disease Management
4. Optimal Drug Use: Population Health and Longitudinal Studies
5. Whole-Person Care: Social Determinants
6. Quality Integration in Health Plan
7. **Preventive Medicine**

Proposal: Use DUR Vital Directions Framework to guide priority area topic clusters

- The Vision
  - Improves health of Medi-Cal beneficiaries by working collaboratively, including FFs and MCOs, to enable and to empower providers and beneficiaries to perform optimally in safe medication use
- Core Goals:
  - Better health and well-being
  - High-value health care
  - Strong science & technology

Ref: Dzau, VJ et al. Vital Directions for Health and Health Care: Priorities From a National Academy of Medicine Initiative. JAMA online March 21, 2017.

Proposal: Use DUR Vital Directions Framework to guide priority area topic clusters (cont.)

- Action Priorities
  - Optimizing Drug Prescribing and Dispensing, including **specialty** drugs
  - Optimizing Pain Management and Opioids
  - Optimizing Chronic Disease Management, including **prevention**
- Essential Infrastructure Needs (Data, Evidence, Education)
  - Measure what matters most
  - Clinical practice guidelines
  - Education and outreach

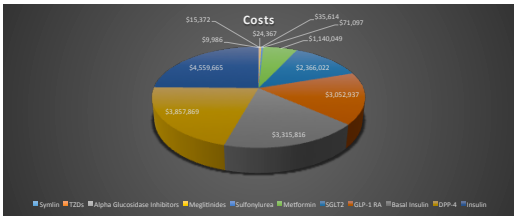
Ref: Dzau, VJ et al. Vital Directions for Health and Health Care: Priorities From a National Academy of Medicine Initiative. JAMA online March 21, 2017.

Questions?

Retrospective DUR Review Proposal: Antihyperglycemic Medications

Robert Mowers, PharmD
Department of Pharmacy Services
UC Davis Health System

2018 Costs: Antihyperglycemic Medications



Proposal

- Conduct a retrospective DUR review of antihyperglycemic medications
  - Global Medi-Cal (FFS and MCP)
  - Include total paid claims, total utilizing beneficiaries, and cost data available to the Board (i.e., AWP or reimbursement paid to pharmacies)
- Work with DUR team to determine medications included in each class
- Present by the November 2019 DUR Board meeting
- Starting point for DUR educational bulletin, outreach opportunities
  - Summarize clinical guidelines/recommendations for pharmacologic approaches to glycemic treatment
  - Target providers using high-cost treatments in patients at high risk of adverse events

Highlights from the Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2017 Annual Report
Prescription Drug Fee-For-Service Programs October 2018

I. Demographics

- All states including the District of Columbia submitted a FFY 2017 Annual Report, with the exception of Arizona because almost all of its beneficiaries are enrolled in managed care organizations (MCOs).
- This summary is focused on Fee-For-Service (FFS) DUR activities. States were not required to submit the specifics of MCO DUR activities for the Federal Fiscal Year (FFY) 2017, but will be required to submit these reports starting with the FFY 2018 Annual Report.

II. Prospective DUR

- California and 44 other states use a vendor to process their point-of-sale claims. Eight states, including California, had a contract with Conduent (formerly Xerox). Magellan had the most state contracts with thirteen.
- California and 36 other states use First Data Bank (FDB) as their ProDUR criteria source.
- For 32 states, the state's DUR board approves new prospective DUR criteria. For California and 17 other states, the approach varied. California's Medi-Cal DUR board advises and makes recommendations for prospective DUR criteria with the final decision coming from the Department of Health Care Services (DHCS).
- California and 43 other states allow pharmacists to override Pro DUR alerts using the "conflict, intervention and outcome" codes.
- California and 6 other states review reports providing individual pharmacy activities in summary and in detail on an annual basis. A total of 14 states review these data monthly, twelve states review these data quarterly, and 17 states never review these data.
    - Eighteen states that receive these reports do not take any follow-up actions. California and 14 other states take follow-up actions with individual pharmacy providers by contacting the pharmacy. Other states use academic detailing or referrals to Program Integrity for review.
- All states set early refill thresholds as a way of preventing prescriptions from being refilled too soon. States reported thresholds ranging from 70% to 93%, with an average of 79% of the prescription being used before a non-controlled prescription could be refilled. For controlled drugs, the range reported is 70% to 100%, with an average of 84% of the prescription being used before the prescription could be refilled. In California, early refill controls are set at 75% for all drugs.

- When an early refill message occurs for non-controlled drugs, a total of 35 states require prior authorization. California does not require prior authorization and allows (along with 9 other states) the pharmacist to override the early refill alert at the point of sale. Five states do not require prior authorization but do not allow the pharmacist to override at the point of sale.
    - For controlled drugs, a total of 41 states require prior authorization. California does not require prior authorization and allows (along with 4 other states) the pharmacist to override the early refill alert at the point of sale.
- Most states did not allow the pharmacist to override early refills due to lost/stolen prescription (n = 36) or for a vacation supply (n = 38). California allows the pharmacist to override both, as long as the prescriptions were medically necessary.
- A total of 21 states have accumulation edits in the system to prevent patients from continuously filling prescriptions early. Some allow for 7 days accumulation over a 120 day look-back period (Arkansas, Alabama), some had limitations on specific therapeutic classes (e.g., Florida – PPIs, skeletal muscle relaxants, and controlled substances), while some had refill too soon carryover days accumulate from month to moth (Illinois). California and 28 other states did not have this edit in place. Out of these 29 states, eleven plan to implement this edit in the future. The current California system does not have this capability.
- California and 26 other states do not have polices prohibiting auto-refill.

III. Retrospective DUR

- California and 8 other states use an academic institution to perform retrospective DUR activities, while 36 states use a vendor to perform retrospective DUR activities.
- A total of 41 states use the retrospective DUR vendor to develop retrospective DUR criteria. The approach varied for the 9 other states, including California. For California, UCSF and DHCS jointly developed the criteria, with input and recommendations from the Medi-Cal DUR board. The final approval of all criteria is made by DHCS.

IV. DUR Board Activity

- California and 18 other states have a disease management program. In California, the DUR Board does not perform the analysis of the program's effectiveness and is not involved in this program.
- A total of 7 states have an approved CMS Medication Therapy Management (MTM) Program. Forty-three states, including California, do not.
- Only Florida and Wisconsin performed an analysis of the MTM program's effectiveness. In Florida, qualitative findings support several benefits based on the members' responses to open-ended questions and survey items, including enhanced medication adherence and greater understanding of their medications. In Wisconsin, the analysis found that the MTM program, while increasing costs overall, might result in improved member health.
- Twelve states, including California, reported future planning to develop and implement a MTM program.

- A total of 12 states incorporate physician-administered drug (PAD) data into their prospective DUR criteria. Thirty-eight states, including California, do not. Of this group, fifteen states, including California, plan to include this information in the future.
- California and 23 other states incorporate PAD data into their retrospective DUR criteria.

VI. Generic Policy and Utilization Data

- California and 43 other states have more restrictive criteria for a brand name drug to be dispensed in lieu of the generic equivalent than prescribers writing "Brand Medically Necessary." For California, if a brand name drug does not appear on the Medi-Cal fee-for-service Contract Drugs List, an approved *Treatment Authorization Request* may be required before dispensing.
- The generic utilization percentage for California was 70%, which remained the same from the prior reporting period, but was still the lowest among all states (average was 83%). Reasons for this might include: 1) California contracts with manufacturers for multisource brand/generic name drugs and is able to contract with brand name manufacturers at a lower cost than a generic, and 2) many carved out-drugs are single-source only and are included in the computation of these data.
- The percentage of dollars paid for generics for California was 8%, which was a 2% decrease from the prior reporting period and is in the bottom five among all states (average was 21%).

VII. Program Evaluation/Cost Savings/Cost Avoidance

- California reported an estimated cost savings/avoidance of $172,247,763 from the prospective DUR program. California did not report cost savings/avoidance from the retrospective DUR program. The percent impact of cost savings/avoidance compared to the total spent on drugs for California was 5%, which represents a decrease of 2% from the previous reporting period. The average cost savings/cost avoidance was 20%, with a range of 0% - 73%. CMS does not specify the standards for the cost savings/avoidance computation, which may explain why there was a wide variation of cost savings/avoidance among the states.

VIII. Fraud, Waste, and Abuse Detection

A. Lock-In or Patient Review and Restrictive Programs

- California and 47 other states have a documented process in place to identify fraud or abuse of controlled drugs by beneficiaries.
- A total of 46 states, not including California, have a "lock-in" program for beneficiaries. Criteria to identify candidates included the number of controlled substances, multiple prescribers, multiple pharmacies, days' supply, exclusivity of short-acting opioids, multiple ER visits, and others.
- California and 36 other states have a documented process in place that identifies possible fraud or abuse of controlled drugs by prescribers.
- California and 34 other states have a documented process in place that identifies potential fraud or abuse of controlled drugs by pharmacy providers.

- California and 24 other states have a documented process in place that identifies potential fraud or abuse of non-controlled drugs.

B. Prescription Drug Monitoring Program (PDMP)

- California and 48 other states have a PDMP. California and 29 other states have the ability to query the state's PDMP database. California and 33 other states do not require prescribers to access the PDMP patient history before prescribing restricted substances.
- California and 28 other states do not have access to border-states' PDMP information.
- California and 45 other states do not require pain management providers to be certified. Only four states have this requirement (New Jersey, Ohio, Tennessee and Texas).
- California and 33 other states do not obtain the DEA Action Controlled Substance Registrant's File to identify prescribers not authorized to prescribe controlled drugs. California and 27 other states do not have plans to obtain the registrant's file and apply it to their POS edits.
- California and 45 other states do not apply the DEA file to their Retro DUR reviews. Only Michigan, New Hampshire, Iowa and Maine apply this file to their Retro DUR reviews.
- California and 42 other states have measures in place to either monitor or manage the prescribing of methadone for pain management. In FFY 2016, California removed methadone from the Medi-Cal fee-for-service Contract Drugs List, making it only available with an approved *Treatment Authorization Request*.

C. Opioids

- California and 39 other states POS edits to limit the quantity of short-acting opioids. States varied in the allowable number of units per day. A total of 18 states set the maximum days supply per prescription at 30 days. In California, short-acting opioids have an established maximum quantity per dispensing and a maximum of three dispensing within a 75-day period.
- California and 38 other states POS edits to limit the quantity of long-acting opioids. States varied in the allowable number of units per day. A total of 24 states allow a maximum of two units/day and 16 states allowed three units per day. A total of 17 states set the maximum days supply per prescription at 30 days. In California, long-acting opioids have an established maximum quantity per dispensing and a maximum of three dispensing within a 75-day period.
- A total of 16 states, not including California, had edits in place to monitor concurrent use of opioids and benzodiazepines. Examples of the edits used by states included: 1) utilizing prior authorization for one or both categories of drugs, 2) asking clinical criteria questions, and 3) using retrospective DUR to generate a near real time intervention letter. Kentucky used prospective DUR edits that required pharmacist intervention for this combination.

D. Morphine Equivalent Daily Dose (MEDD)

- A total of 24 states, not including California, have set a recommended maximum MEDD. The lowest maximum MEDD was Maine (30 mg) and the highest was Colorado (300mg). The median MEDD was 110 mg. The following table shows states recommended maximum MEDD

AR	CO	DE	ID	IN	LA	MA	MD	ME	MI	MN	NC	ND	NV	OH	OK	OR	PA	TN	VA	VT	WA	WV	WY
250	300	120	90	60	90	120	90	30	120	120	120	90	60	80	120	90	50	200	120	50	120	50	120

- California and 23 other states provided information to prescribers on how to calculate MEDD. A total of 14 states, not including California, posted the calculator on their website. Others provided information in various ways such as provider notice (Michigan, Vermont, and Virginia), educational bulletin (California, Indiana, and Maryland), and targeted letters to prescribers (Idaho, Indiana, and Virginia).
- A total of 17 states had an algorithm in the state's POS system that alerted the pharmacy provider that the MEDD prescribed was exceeded. California and 32 other states did not have an algorithm in place to alert the pharmacy.

E. Buprenorphine and Buprenorphine/Naloxone Combinations

- California and 42 other states set total mg/day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs, with the maximum total mg/day ranging from 12 mg/day to 48 mg/day. California has a maximum quantity of four dosage units per day, regardless of strength, and a maximum allowable total daily dose of 48 mg.
- California and 34 other states have no limit on the allowable length of treatment with buprenorphine. California and 38 other states do not require that the maximum mg/day allowable be reduced after a set period.
- California and 44 other states had at least one preferred buprenorphine/naloxone combination product on preferred drug list.
- A total of 33 states have edits in place to monitor use of opioids concurrently with any buprenorphine drug. Only five of these states allow override (Maryland, Rhode Island, Virginia, Vermont and DC). California and 16 other states do not have edits in place to monitor opioids being used concurrently with any buprenorphine drug.

F. Antipsychotics/Stimulants

- California and 42 other states have a documented program in place to either manage or monitor the use of antipsychotic drugs in children. Most states monitor all children, except for Delaware, Montana and Oregon, which monitor children in foster care only.
- The majority of states, including California, have edits in place to monitor age, dosage, and polypharmacy.
- California and 47 other states had documented restrictions or special programs in place to monitor, manage or control the use of stimulants. Only two states did not (Maryland and North Carolina).

IX. Innovative Practices

- California and 38 other states provided a description of their innovative practices during the reporting year.

X. E-Prescribing

- A total of 24 states have a portal to electronically provide patient drug history data and pharmacy coverage limitations to a prescriber prior to prescribing, upon inquiry. Seven of these states explained their e-prescribing evaluation methodology in greater detail. California and 25 other states do not have this capability.
- A total of 37 states, not including California, use the NCPDP Origin Code that indicates the prescription source.

XI. Managed Care Organizations (MCOs)

- California and 37 other states have MCOs.
    - A total of 17 states include the pharmacy program in the capitation rate (carved-in)
    - A total of 5 states did not include the pharmacy program in the capitation rate
    - California and 15 other states have a pharmacy program that was partially included in the capitation rate. There were variations in what was included and not included. For California, the carved out drugs are selected HIV/AIDS, selected alcohol and heroin detoxification and dependency/treatment drugs, selected coagulation factors, and selected drugs to treat psychiatric conditions.
- California and 19 other states set requirements for the MCO pharmacy benefit, with requirements differing from state to state.
    - Formulary review is a requirement for California, DC, Delaware, Florida, Illinois, Maryland, Michigan, New England, New Jersey, New York, Ohio, Pennsylvania, Texas, Utah, and Washington
    - A total of 9 states required the same preferred drug list as the fee-for-service program (Delaware, Florida, Iowa, Kansas, Mississippi, New England, Texas, Utah, and West Virginia).
    - A total of 4 states require the same retrospective DUR criteria (Colorado, Iowa, Florida and Utah). Five states required the same prospective DUR criteria (Colorado, Iowa, Kansas, Florida, and Utah).
    - In California, MCOs are required to provide a pharmacy benefit that is comparable to the Medi-Cal FFS pharmacy program and their preferred drug lists PDLs are required to be comparable to the Medi-Cal fee-for-service List of Contract Drugs. While all drugs included on the Medi-Cal fee-for-service List of Contract Drugs do not need to be included on the MCOs' PDLs, comparable means that the drugs on the PDLs must have the same mechanism of action sub-class within all major therapeutic categories of drugs included in the Medi-Cal fee-for-service List of Contract Drugs.
- California and 13 other states require their MCOs to report their DUR activities. In California, MCOs are required to submit Policies and Procedures for DUR and treatment outcomes system to optimize the quality of pharmacy services.

CMS DUR Annual Report FFY 2018

Pauline Chan, R.Ph., MBA, DHCS
Hannah Orozco, Pharm.D., Conduent
February 26, 2019

Introduction

- CMS DUR Annual Report
- 42 CFR Subpart K Section 456.700-456.725
- Report has three parts:
  - Survey
  - Attachments
  - Tables (2)

Overview

- Medi-Cal DUR Annual Report to CMS FFY 2018
  - Reporting period: October 1, 2017- September 30, 2018
  - Includes both FFS and MCOs
- Today's presentation is FFS only
- May 2018 board meeting to include MCO reports
- Report (as one single submission) due to CMS by July 1, 2019

Section One: Survey Questionnaire - 1

- Prospective DUR
  - Early Refill
  - Auto-Refill
  - Refill Synchronization
- Retrospective DUR
  - Educational outreach summary

Section One: Survey Questionnaire - 2

- DUR Board Activity
  - Summary
- Physician Administered Drugs
  - Paid through the physician and hospital programs
  - Inclusion/Exclusion in the prospective and retrospective DUR review

Section One: Survey Questionnaire - 3

- Generic Policy and Utilization Data
  - Policy
  - Included in Table 2 - Generic Utilization Data
    - Number of generic claims
    - Total number of claims
    - Generic utilization percentage
    - Generic dollars
    - Total dollars
    - Generic expenditure percentage

Section One: Survey Questionnaire - 4

- Program Evaluation/Cost Savings/Cost Avoidance
  - Use prospective DUR to estimate avoidance costs
  - The percentage of estimated cost avoidance/cost savings is derived from dividing the total estimate avoidance cost by the total expenditure dollars

Section One: Survey Questionnaire - 5

- Fraud, Waste, and Abuse Detection
  - A. Lock-In Program
  - B. Prescription Drug Monitoring Program (PDMP)
  - C. Pain Management Controls
  - D. Opioids
  - E. Morphine Equivalent Daily Dose
  - F. Buprenorphine and Buprenorphine/Naloxone Combinations
  - G. Antipsychotics/Stimulants

Section One: Survey Questionnaire - 6

- Innovative Practices
- Electronic Prescribing
- Managed Care Organizations

Section Two: Survey Attachments - 1

1. Pharmacy Oral Counseling Compliance
2. Retrospective DUR Educational Outreach
   - Six educational outreach bulletins with recommendations published on webpage
   - Three outreach letters
     - Two to prescribers
     - One to pharmacies
3. DUR Board Activities
   - Ongoing DUR board projects

Section Two: Survey Attachments - 2

4. Generic Drug Substitution Policy
   - Restrictions to the Medi-Cal FFS Contract Drugs List
   - Carved-out drug benefits
   - Policies to encourage generic equivalent substitution
     - California Business and Professional Codes Section 4073
   - Policies affecting generic utilization rate
     - Reimbursement

Section Two: Survey Attachments - 3

5. Cost Savings/Cost Avoidance Methodology
   - Assumption:
     - When DUR alerts and educational bulletins are reviewed as intended, notification of a potential drug therapy problem through a DUR alert or the knowledge gained from educational bulletins will lead to appropriate action
   - Methodology:
     - Count the number of claims cancelled or not overridden as flagged by alerts
     - Estimate the average reimbursement dollars paid per claim
     - Use a multiplier to determine cost savings on a more conservative side
     - Estimate costs avoidance of program

Section Two: Survey Attachments - 4

6. Innovative Practices
   - Prescription drug overdose
   - Development of a companion guide/FAQ for the 2018 DUR Annual Report
   - Academic Detailing
   - Tobacco Control
7. Executive Summary
   - The report is a collaboration of the Department of Health Care Services, the Global Medi-Cal DUR Board, Conduent, and the University of California, San Francisco

Section Three: Tables

- Table 1 – Top Drugs Claims Data
  - Most are carved-out drugs
  - Ranked by total expenditure by amount reimbursed and by total number of paid claims
- Table 2 – Generic Utilization Data

Summary

- For the first time, FFY 2018 annual report will include both FFS and MCOs
- Opportunities for Medi-Cal to share best practices between FFS and MCOs
- CMS will continue to publish state comparison reports, and will include new information from MCOs
- Complete report (FFS and MCOs) will be presented at May 2019 Board Meeting

Questions?

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State of California
MEDICAID DRUG UTILIZATION REVIEW

Centers for Medicare & Medicaid Services
Federal Fiscal Year 2018

ANNUAL REPORT
FEDERAL FISCAL YEAR 2018

This report covers the period
October 1, 2017 to September 30, 2018

The Great Seal

Department of Health Care Services

Prepared by

Medi-Cal DUR

UCSF
University of California
San Francisco

Under the direction of the Medi-Cal Pharmacy Benefits Division, Pharmacy Policy Branch, and the Global Medi-Cal Drug Use Review Board

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Global Medi-Cal
Drug Use Review (DUR) Program
Federal Fiscal Year (FFY) 2018 Annual Report
October 1, 2017 to September 30, 2018

TABLE OF CONTENTS

CMS SURVEY

I. DEMOGRAPHIC INFORMATION

State Name Abbreviation: CA

Medicaid Agency Information: Identify State person responsible for DUR Annual Report Preparation.

Name: Ivana Thompson, PharmD
Email Address: Ivana.Thompson@dhcs.ca.gov
Area Code/Phone Number: (916) 345-8642

1. On average, how many beneficiaries are enrolled in your state's Medicaid Fee-for-Service (FFS) program that have a pharmacy benefit? 2,373,221 beneficiaries

2. On average, how many of your state's Medicaid beneficiaries are enrolled in managed care plan(s)? 10,779,691 beneficiaries

II. PROSPECTIVE DUR (ProDUR)

1. Identify by name and indicate the type of your pharmacy POS vendor - (contractor, state-operated, or other organization).

   Contractor: Conduent

2. If not state-operated, is the POS vendor also the MMIS fiscal agent?

   ☒Yes ☐No

3. Identify prospective DUR criteria source.

   ☒ First Data Bank ☐Medi-Span ☐Other

   If the answer above is "Other," please specify:

   _____

4. Are new ProDUR criteria approved by the DUR Board?

   ☐Yes ☒No

   If answer above is "No," please explain:

   The DUR Board advises and makes recommendations regarding prospective DUR criteria; however, final approval is made by DHCS.

5. When the pharmacist receives a level-one ProDUR alert message that requires a pharmacist's review, does your system allow the pharmacist to override the alert using the "NCPDP drug use evaluation codes" (reason for service, professional service, and resolution)?

☒Yes ☐No ☐Partial

If you answered "partial," please explain:

_____

6. Do you receive and review follow-up periodic reports providing individual pharmacy provider activity in summary and/or in detail?

☒Yes ☐No

a) If the answer is "Yes," how often?

☐ Monthly ☐ Quarterly ☒ Annually ☐ Other, please explain.

_____

b) If the answer above is "No," please explain.

_____

c) If you receive reports, do you follow-up with those providers who routinely override with interventions?

☒Yes ☐No

d) If the answer to (6c) above is "Yes," by what method do you follow-up?

☒ Contact Pharmacy
☐ Refer to Program Integrity for Review
☐ Other, please explain.

_____

e) If the answer to (6c) above is "No," please explain why you do not follow-up with providers.

_____

7. Early Refill:

a) At what percent threshold do you set your system to edit?

Non-controlled drugs:	75%
Schedule II Controlled drugs:	75%
Schedule III through V Controlled drugs:	75%

b) When an early refill message occurs, does the state require prior authorization?

Non-controlled drugs: ☐Yes ☒No

c) When an early refill message occurs, does the state require prior authorization?

Controlled drugs: ☐Yes ☒No

d) For non-controlled drugs, if the answer to (7b) above is "Yes," who obtains authorization?

☐ Pharmacist ☐ Prescriber ☐ Either

e) For controlled drugs, if the answer to (7c) above is "Yes," who obtains authorization?

☐ Pharmacist ☐ Prescriber ☐ Either

f) For non-controlled drugs, if the answer to (7b) above is "No," can the pharmacist override at the point of service?

☒Yes ☐No

g) For controlled drugs, if the answer to (7c) above is "No," can the pharmacist override at the point of service?

☒Yes ☐No

8. When the pharmacist receives an early refill DUR alert message that requires the pharmacist's review, does your state's policy allow the pharmacist to override for situations such as:

a) Lost/stolen Rx ☒Yes ☐No
b) Vacation ☒Yes ☐No
c) Other, please explain. The pharmacist can override the early refill DUR alert message if medically necessary.

9. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?

☐Yes ☒No

a) If "Yes," please explain your edit.

_____

b) If "No," do you plan to implement this edit? ☐Yes ☒No

10. Does the state Medicaid agency or the state's Board of Pharmacy have any policy prohibiting the auto-refill process that occurs at the POS (i.e., must obtain beneficiary's consent prior to enrolling in the auto-refill program)?

☐Yes ☒No

11. Does the state Medicaid agency have any policy that provides for the synchronization of prescription refills (i.e., if the patient wants and pharmacy provider permits the patient to obtain non-controlled, chronic medication refills at the same time, the state would allow this to occur to prevent the beneficiary from making multiple trips to the pharmacy within the same month)?

☐Yes ☒No

12. Has the state provided DUR data requested on **Table 1 – Top Drug Claims Data Reviewed by the DUR Board?**

☒Yes ☐No

13. Section 1927(g)(A) of the Social Security Act requires that the pharmacist offer patient counseling at the time of dispensing. Who in your state has responsibility for monitoring compliance with the oral counseling requirement? Check all that apply:

a) ☐ Medicaid agency
b) ☒ State Board of Pharmacy
c) ☐ Other, please explain.

_____

14. Has the state included **Attachment 1 – Pharmacy Oral Counseling Compliance Report**, a report on state efforts to monitor pharmacy compliance with the oral counseling requirement?

☒Yes ☐No

III. RETROSPECTIVE DUR (RetroDUR)

1. Identify, by name and type, the vendor that performed your Retro DUR activities during the time period covered by this report (company, academic institution, or other organization).

Academic institution: University of California, San Francisco (UCSF)

2. Who reviews and approves the RetroDUR criteria?

☐ State DUR board ☒ Other

If "Other," please explain:

Retrospective DUR criteria are developed jointly by UCSF and DHCS with input and recommendation by the DUR board. Final approval of criteria is made by DHCS.

3. Has the state included **Attachment 2 -Retrospective DUR Educational Outreach Summary**, a year end summary of the Top 10 problem types for which educational interventions were taken?

☒Yes ☐No

IV. DUR BOARD ACTIVITY

1. Has the state included a brief summary of DUR Board activities during the time period covered by this report as **Attachment 3 – Summary of DUR Board Activities**?

☒Yes ☐No

2. Does your state have an approved CMS Medication Therapy Management Program?

☐Yes ☒No

a) If "Yes", have you performed an analysis of the program's effectiveness?

☐Yes ☐No

b) If the answer to (2a) above is "Yes", please provide a brief summary of your findings:

_____

c) If the answer to (number 2) above is "Yes," is your DUR Board involved with this program?

☐Yes ☐No

d) If the answer to (number 2) above is "No," are you planning to develop and implement a program?

☒Yes ☐No

V. PHYSICIAN ADMINISTERED DRUGS

The Deficit Reduction Act required collection of NDC numbers for covered outpatient physician administered drugs. These drugs are paid through the physician and hospital programs. Has your MMIS been designed to incorporate this data into your DUR criteria for:

1. ProDUR?

☐Yes ☒No

If "No," do you have a plan to include this information in your DUR criteria in the future?

☐Yes ☒No

2. RetroDUR?

☒Yes ☐No

If "No," do you have a plan to include this information in your DUR criteria in the future?

☐Yes ☐No

VI. GENERIC POLICY AND UTILIZATION DATA

1. Has the state included a description of policies that may affect generic utilization percentage as **Attachment 4 - Generic Drug Substitution Policies**?

☒Yes ☐No

2. In addition to the requirement that the prescriber write in his own handwriting "Brand Medically Necessary" for a brand name drug to be dispensed in lieu of the generic equivalent, does your state have a more restrictive requirement?

☒Yes ☐No

If "Yes", check all that apply:

a) ☐ Require that a MedWatch Form be submitted
b) ☐ Require medical reason for override accompany prescriptions
c) ☐ Prior authorization is required
d) ☒ Other, please explain.

If a brand name drug does not appear on the Medi-Cal List of Contract Drugs, an approved *Treatment Authorization Request* demonstrating medical necessity may be required before dispensing.

3. Indicate the generic utilization percentage for all covered outpatient drugs paid during this reporting period, using the computation instructions in **Table 2 – Generic Utilization Data**.

   Number of Generic Claims: 7,598,080

   Total Number of Claims: 10,935,201

   Generic Utilization Percentage: 69.5%

4. Indicate the percentage dollars paid for generic covered outpatient drugs in relation to all covered outpatient drug claims paid during this reporting period using the computation instructions in **Table 2 - Generic Utilization Data**.

   Generic Dollars: $266,496,188

   Total Dollars: $3,710,975,893

   Generic Expenditure Percentage: 7.2%

VII. PROGRAM EVALUATION/COST SAVINGS/COST AVOIDANCE

1. Did your state conduct a DUR program evaluation of the estimated cost savings/cost avoidance?

   ☒Yes ☐No

2. Who conducted your program evaluation for the cost savings estimate/cost avoidance (company, academic institution, other institution) and (name of the entity)?

   Academic institution: University of California, San Francisco (UCSF)

3. Please provide your ProDUR and RetroDUR program cost savings/cost avoidance in the chart below.

ProDUR Total Estimated Avoided Costs	$223,974,640
RetroDUR Total Estimated Avoided Costs	$0
Other cost avoidance	$0
Grand Total estimated Avoided Costs	**$223,974,640**

4. Please provide the estimated percent impact of your state's cost savings/cost

avoidance program compared to total drug expenditures for covered outpatient drugs.

Use the following formula:

Divide the estimated Grand Total Estimated Avoided Costs from Question 3 above by the total dollar amount provided in Section VI, Question 4. Then multiply this number by 100.

Grand Estimated Net Savings Amount ÷ Total Dollar Amount × 100 = **6.0%**
($223,974,640 ÷ $3,710,975,893 × 100 = 6.0%)

5. State has provided the Medicaid Cost Savings/Cost Avoidance Evaluation as **Attachment 5 – Cost Savings/Cost Avoidance Methodology**.

☒Yes ☐No

VIII. FRAUD, WASTE, AND ABUSE DETECTION

A. LOCK-IN or PATIENT REVIEW AND RESTRICTIVE PROGRAMS

1. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by **beneficiaries**?

☒Yes ☐No

If "Yes," what action(s) does this process initiate? Check all that apply.

a) ☐ Deny claim and require prior authorization
b) ☐ Refer recipient to Lock In Program
c) ☐ Refer to Program Integrity Unit
d) ☒ Other (e.g. SURS, Office of Inspector General), please explain.

22CCR §50793 details available utilization restrictions when the Department has determined that a beneficiary is misusing or abusing Medi-Cal benefits. Audit & Investigations, Investigations Branch (IB) is responsible for working beneficiary cases. IB has an intake process for complaints which entails an initial case review and if warranted, assignment of a case to an investigator. Subsequent actions are dependent upon the outcome of IB's investigation.

2. Do you have a "lock-in" program for beneficiaries with potential misuse or abuse of controlled substances?

☐Yes ☒No

a) If "Yes", what criteria does your state use to identify candidates for lock-in?

Check all that apply.

- ☐ Number of controlled substances (CS)
- ☐ Different prescribers of CS
- ☐ Multiple pharmacies
- ☐ Number days' supply of CS
- ☐ Exclusivity of short acting opioids
- ☐ Multiple ER visits
- ☐ PDMP data
- ☐ Other, please explain.

_____

b) If "Yes" do you restrict the beneficiary to:

- prescriber only ☐Yes ☐No
- pharmacy only ☐Yes ☐No
- prescriber and pharmacy ☐Yes ☐No

c) If the answer to (number 2) above is "Yes," what is the usual "lock-in" time period?

- ☐ 12 months
- ☐ 18 months
- ☐ 24 months
- ☐ Other, please explain.

_____

3. If the answer to (number 2) above is "Yes," on average, what percentage of the FFS population is in lock-in status annually? _____%

4. If the answer to (number 2) above is "Yes," please provide an estimate of the savings attributed to the lock-in program for the fiscal year under review as part of Attachment 5.

   $_____

5. Do you have a documented process in place that identifies possible fraud or abuse of controlled drugs by **prescribers**?

   ☒Yes ☐No

   If "Yes," what actions does this process initiate? Check all that apply.

   a) ☒ Deny claims written by this prescriber
   b) ☒ Refer to Program Integrity Unit
   c) ☐ Refer to the appropriate Medical Board

d) ☒ Other, please explain.

Propose new policy such as quantity restrictions, and further review by Audit & Investigations, Investigations Branch (IB) and Medical Review Branch (MRB).

6. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by **pharmacy providers**?

☒Yes ☐No

If "Yes," what actions does this process initiate? Check all that apply.

a) ☐ Deny claim
b) ☒ Refer to Program Integrity Unit
c) ☐ Refer to Board of Pharmacy
d) ☒ Other, please explain.

Propose new policy such as quantity restrictions and further review by Audit & Investigations, Investigations Branch (IB) and Medical Review Branch (MRB).

7. Do you have a documented process in place that identifies potential fraud or abuse of non-controlled drugs by **beneficiaries**?

☒Yes ☐No

If "Yes," please explain your program for fraud, waste, or abuse of non-controlled substances.

Audit & Investigations, Investigations Branch (IB) uses all available information to develop and work cases, initiates audits, and assists in investigations, including review of claims data and trends of non-controlled drugs.

B. PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

1. Does your state have a Prescription Drug Monitoring Program (PDMP)?

☒Yes ☐No

a) If the answer above is "Yes" does your agency have the ability to query the state's PDMP database?

☒Yes ☐No

b) If the answer to (number 1) above is "Yes", do you require prescribers (in your provider agreement with the agency) to access the PDMP patient history before

prescribing restricted substances?

☐Yes ☒No

c) If the answer to (number 1a) above is "Yes", please explain how the state applies this information to control fraud and abuse.

The California Department of Justice has a Prescription Drug Monitoring Program (PDMP) system called the Controlled Substance Utilization Review and Evaluation System (CURES), which allows pre-registered users including licensed healthcare prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards to access timely patient controlled substance history information.

Access to such information helps prescribers and pharmacists better evaluate their patients' care, allowing them to make better prescribing and dispensing decisions, and cut down on prescription drug abuse in California.

Audit & Investigations, Investigations Branch (IB) uses all available information to develop and work cases, initiates audits, and assists in investigations. IB also examines PDMP information on prescribers, dispensers, and beneficiaries during the course of their usual work.

d) If the answer to (number 1a) above is "Yes", do you also have access to border states' PDMP information?

☐Yes ☒No

e) If the answer to (number 1a) above is "Yes", do you also have PDMP data (i.e., outside of MMIS, such as a controlled substance that was paid for by using cash) integrated into your POS edits?

☐Yes ☒No

f) If the answer to (number 1) above is "Yes", are there barriers that hinder the agency from fully accessing the PDMP that prevent the program from being utilized the way it was intended to be to curb abuse?

☒Yes ☐No

g) If the answer to (f) above is "Yes", please explain the barriers (i.e., lag time in prescription data being submitted, prescribers not accessing, pharmacists unable to view prescription history before filling script).

The following barriers exist that hinder the agency from fully accessing the PDMP in the way it was intended:

- Inability to access border states' PDMP information
- Lag time for prescription data being submitted
- Ambiguous regulations governing access to PDMP data

2. Have you had any changes to your state's Prescription Drug Monitoring Program during this reporting period that have improved the agency's ability to access PDMP data?

☒Yes ☐No

If "Yes" please explain.

In 2016, California updated their prescription drug monitoring program, the Controlled Substance Utilization Review and Evaluation System (CURES), to CURES 2.0. Pursuant to Section 11165.4(e) of the Health and Safety Code, this upgraded database was certified for statewide use by the Department of Justice on April 2, 2018.

As a result of the certification that took place in FFY 2018, effective for dates of service on or after October 2, 2018, it will be mandatory to consult the CURES 2.0 database prior to prescribing, ordering, administering, or furnishing a Schedule II – IV controlled substance.

C. PAIN MANAGEMENT CONTROLS

1. Does your program obtain the DEA Active Controlled Substance Registrant's File in order to identify prescribers not authorized to prescribe controlled drugs?

☐Yes ☒No

a) If the answer above is "Yes," do you apply this DEA file to your ProDur POS edits to prevent unauthorized prescribing?

☐Yes ☐No

b) If the answer to (a) above is "Yes," please explain how the information is applied

_____

c) If the answer to (a) above is "No" do you plan to obtain the DEA Active Controlled Substance Registrant's file and apply it to your POS edits?

☐Yes ☐No

2. Do you apply this DEA file to your RetroDUR reviews?

☐Yes ☒No

If "Yes" please explain how it is applied.

---

3. Do you have a measure (i.e., prior authorization, quantity limits) in place to either monitor or manage the prescribing of methadone for pain management?

☒Yes ☐No

If "No," please explain why you do not have a measure in place to either manage or monitor the prescribing of methadone for pain management.

D. OPIOIDS

1. Do you currently have POS edits in place to limit the quantity dispensed of an initial opioid prescription?

☐Yes for all opioids ☒Yes for some opioids ☐No for all opioids

a) If there is more than one quantity limit for the various opioids please explain.

Opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.

b) What is the maximum number of days allowed for an initial opioid prescription?

_100_ # of days

c) If you have different days allowed for the initial limit for the various opioids, please explain.

---

2. For subsequent prescriptions, do you have POS edits in place to limit the quantity dispensed of short-acting opioids?

☒Yes ☐No

a) If "Yes" what is your maximum days supply per prescription limitation?

☐ 30 day supply
☐ 90 day supply

☒ Other, please explain: Short-acting opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.

3. Do you currently have POS edits in place to limit the quantity of long-acting opioids?

☒Yes ☐No

a) If "Yes" what is your maximum days supply per prescription limitation?

☐ 30 day supply
☐ 90 day supply
☒ Other, please explain: Long-acting opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.

4. Do you have measures other than restricted quantities and days supply in place to either monitor or manage the prescribing of opioids?

☒Yes ☐No

a) If "Yes," please check all that apply:

☐ Pharmacist override
☐ Deny claim and require PA
☒ Intervention letters
☐ Morphine equivalent daily dose (MEDD) program
☐ Step therapy or Clinical criteria
☐ Requirement that patient has a pain management contract or Patient-Provider agreement
☐ Requirement that prescriber has an opioid treatment plan for patients
☐ Require documentation of urine drug screening results
☒ Other, please explain what additional opioid prescribing controls are in place: California has a Statewide Opioid Safety (SOS) Workgroup to improve coordination and expand joint efforts to address opioid misuse, addiction, and overdose deaths.

b) If the answer to (number 4) above is "No," please explain what you do in lieu of the above or why you do not have measures in place to either manage or monitor the prescribing of opioids.

---

5. Do you currently have edits in place to monitor opioids and benzodiazepines being used concurrently?

☒Yes ☐No

If "Yes" please explain.

Effective June 1, 2018, the Medi-Cal fee-for-service prospective DUR system was updated to generate an alert for additive toxicity (AT) when a patient reaches a threshold of four active prescriptions within the following therapeutic categories: opioid pain or cough medications, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with central nervous system (CNS) depressant properties.

6. Do you perform any RetroDUR activity and/or provider education in regard to beneficiaries with a diagnosis history of opioid use disorder (OUD) or opioid poisoning diagnosis?

☒Yes ☐No

a) If the answer to (number 6) above is "Yes," please indicate how often.

☐ Monthly ☐ Quarterly ☒ Annually ☐ Other, please explain.

_____

b) If the answer to (number 6) above is "No," do you plan on implementing a RetroDUR activity and/or provider education in regard to beneficiaries with a diagnosis history of OUD or opioid poisoning in the future?

☐Yes ☐No

7. Does your state Medicaid agency develop and provide prescribers with pain management or opioid prescribing guidelines?

☒Yes ☐No

a) ☒ Does your state Medicaid agency refer prescribers to the CDC's Guideline for Prescribing Opioids for Chronic Pain?
b) ☒ Other guidelines
c) ☐ No guidelines are offered
d) ☐ Please identify "other" or "referred" guidelines:
The Medical Board of California Guidelines for Prescribing Controlled Substances for Pain.

8. Do you have a drug utilization management strategy that supports abuse deterrent opioid use to prevent opioid misuse and abuse (i.e. presence of an abuse deterrent opioid with preferred status on your preferred drug list)?

☒Yes ☐No

If "Yes," please explain.

Effective August 1, 2017, multiple strengths of morphine sulfate/naltrexone were added to the Medi-Cal List of Contract Drugs.

E. MORPHINE EQUIVALENT DAILY DOSE (MEDD)

1. Have you set recommended maximum morphine equivalent daily dose measures?

☐Yes ☒No

a) If "Yes," what is your maximum morphine equivalent daily dose limit in milligrams?

_____mg per day

b) If "Yes," please explain (i.e. are you in the process of tapering patients to achieve this limit)?

_____

c) If "No," please explain the measure or program you utilize.

All opioids have an established maximum quantity per dispensing and a maximum of three (3) dispensings within any 75-day period.

2. Do you provide information to your prescribers on how to calculate the morphine equivalent daily dosage or do you provide a calculator developed elsewhere?

☒Yes ☐No

Please name the developer of the calculator: 1) the New York City Department of Health and Mental Hygiene (DOHMH); 2) the Washington State Agency Medical Directors' Group; and 3) the Centers for Disease Control and Prevention

If "Yes" how is the information disseminated?

☐ Website
☐ Provider notice
☐ Educational seminar
☒ Other, please explain.

The Medi-Cal DUR program published an educational bulletin entitled, "*Clinical Review: Morphine Equivalent Daily Dose to Prevent Opioid Overuse"* to the Medi-Cal DUR website. This bulletin defined morphine equivalent daily dose (MEDD) and provided evidence to support using MEDD as an indicator of potential dose-related

risk for prescription opioid overdose. The bulletin provided links to several online MEDD calculators, as well as additional resources to providers. The bulletin was also emailed to all providers who subscribe to the Medi-Cal Subscription Service.

3. Do you have an algorithm in your POS system that alerts the pharmacy provider that the morphine equivalent daily dose prescribed has been exceeded?

☐Yes ☒No

If "Yes," do you require prior authorization if the MEDD limit is exceeded?

☐Yes ☐No

F. BUPRENORPHINE and BUPRENORPHINE/NALOXONE COMBINATIONS

1. Does your agency set total mg per day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs?

☒Yes ☐No

If "Yes", please specify the total mg/day?

☐ 12 mg
☐ 16 mg
☐ 24 mg
☒ Other, please explain: There is a maximum quantity of four dosage units per day, regardless of strength. The maximum allowable total daily dose is 48 mg.

2. What are your limitations on the allowable length of this treatment?

☐ 6 months
☐ 12 months
☒ No limit
☐ Other, please explain.

3. Do you require that the maximum mg per day allowable be reduced after a set period of time?

☐Yes ☒No

a) If "Yes," what is your reduced (maintenance) dosage?
   ☐ 8 mg
   ☐ 12 mg
   ☐ 16 mg
   ☐ Other, please explain.

b) If "Yes," what are your limitations on the allowable length of the reduced dosage treatment?

☐ 6 months
☐ 12 months
☐ No limit
☐ Other, please explain.

4. Do you have at least one preferred buprenorphine/naloxone combination product available without prior authorization?

☒Yes ☐No

5. Do you currently have edits in place to monitor opioids being used concurrently with any buprenorphine drug?

☐Yes ☒No ☐ Other, please explain.

If "Yes," can the POS pharmacist override the edit?

☐Yes ☐No

6. Do you have at least one naloxone opioid overdose product available without prior authorization?

☒Yes ☐No

7. Does your state board of pharmacy and/or state Medicaid agency allow pharmacists to dispense naloxone prescribed independently or by collaborative practice agreements, standing orders, or other predetermined protocols?

☒Yes ☐No

8. Does your state agency cover Methadone for a substance use disorder (i.e. Methadone Treatment Center)?

☒Yes ☐No

G. ANTIPSYCHOTICS/STIMULANTS

ANTIPSYCHOTICS

1. Do you currently have restrictions in place to limit the quantity of antipsychotics?

   ☐Yes ☒No

   If restriction is other than quantity limit, please explain.
   An approved *Treatment Authorization Request* is required for any antipsychotic medication for all Medi-Cal beneficiaries 0 – 17 years of age. An approved *Treatment Authorization Request* is also required for beneficiaries residing in skilled nursing facilities (SNFs).

2. Do you have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children??

   ☒Yes ☐No

   a) If "Yes," do you either manage or monitor:

   ☐ Only children in foster care
   ☒ All children
   ☐ Other, please explain.

   ---

   b) If "Yes," do you have edits in place to monitor (check all that apply):

   ☒ Child's Age ☒ Dosage ☒ Polypharmacy ☒ Other

   Please briefly explain the specifics of your antipsychotic monitoring program(s).

   An approved *Treatment Authorization Request* is required for any antipsychotic medication for all Medi-Cal beneficiaries 0 – 17 years of age.

   In addition, DHCS Pharmacy Benefits Division, DHCS Behavioral Health Division, and California Department of Social Services (CDSS) continue to collaborate on a Quality Improvement Project entitled, "Improving the Use of Psychotropic Medication among Children and Youth in Foster Care." The purpose of this program is to reduce the rate of antipsychotic polypharmacy, improve the rate of compliance with age-specific antipsychotic dose recommended guidelines, and improve the rate of children and youth in foster care with at least one psychotropic medication who have an annual metabolic risk assessment. The goals are to reduce polypharmacy and improve compliance with dosing guidelines and annual metabolic risk assessment.

   c) If you do not have an antipsychotic monitoring program in place, do you plan on implementing a program in the future?

☐Yes ☐No

d) If "No," please explain why you will not be implementing a program to monitor the appropriate use of antipsychotic drugs in children.

STIMULANTS

3. Do you currently have restrictions in place to limit the quantity of stimulants?

☐Yes ☒No

4. Do you have any documented program in place to either manage or monitor the appropriate use of stimulant drugs in children?

☒Yes ☐No

a) If "Yes," do you either manage or monitor:

☐ Only children in foster care
☒ All children
☐ Other, please explain.

b) If "Yes," do you have edits in place to monitor (check all that apply):

☒ Child's Age ☐ Dosage ☐ Polypharmacy ☒ Other

Please briefly explain the specifics of your antipsychotic monitoring program(s).

The use of stimulants for Medi-Cal beneficiaries is restricted to use in Attention Deficit Disorder in individuals from 4 years through 16 years of age only. Any use outside of these restrictions requires an approved *Treatment Authorization Request*.

c) If you do not have a documented stimulant monitoring program in place, do you plan on implementing a program in the future?

☐Yes ☐No

d) If "No," please explain why you will not be implementing a program to monitor the appropriate use of stimulant drugs in children.

IX. INNOVATIVE PRACTICES

Have you developed any innovative practices during the past year which you have included in **Attachment 6 - Innovative Practices** (i.e., Substance Use Disorder, Hepatitis C, Cystic Fibrosis, MEDD, Value Based Purchasing)?

☒Yes ☐No

X. E-PRESCRIBING

1. Does your MMIS or pharmacy vendor have a portal to electronically provide patient drug history data and pharmacy coverage limitations to a prescriber prior to prescribing upon inquiry?

   ☐Yes ☒No

   a) If "Yes," do you have a methodology to evaluate the effectiveness of providing drug information and medication history prior to prescribing?

      ☐Yes ☐No

   b) If "Yes," please explain the evaluation methodology in **Attachment 7 – E-Prescribing Activity Summary**.

   c) If the answer to (number 1) above is "No," are you planning to develop this capability?

      ☐Yes ☒No

2. Does your system use the NCPDP Origin Code that indicates the prescription source?

   ☐Yes ☒No

XI. MANAGED CARE ORGANIZATIONS (MCOs)

1. How many MCOs are enrolled in your state Medicaid program?

   __25__ MCO(s) (Insert number of MCOs in the blank including 0 if none)

   If "Zero" or "None," please skip the rest of this section.

2. Is your pharmacy program included in the capitation rate (carved in)?

   ☐Yes ☐No ☒Partial

If "partial," please specify the drug categories that are carved out.

- Selected HIV/AIDS/Hepatitis B treatment drugs;
- Selected alcohol and heroin detoxification and dependency treatment drugs;
- Selected coagulation factors; and
- Selected drugs used to treat psychiatric conditions (including antipsychotics and MAO inhibitors)

3. Does the state set requirements for the MCO's pharmacy benefit (i.e., same PDL, same ProDUR/RetroDUR)?

☒Yes ☐No

If "Yes," do please check all requirements that apply below:

☒ Formulary Reviews ☐ Same PDL ☐ Same ProDUR ☐ Same RetroDUR

If "Yes," please briefly explain your policy:

Medi-Cal MCOs are required to provide a pharmacy benefit that is comparable to the Medi-Cal FFS pharmacy program and their preferred drug lists (PDLs) are required to be comparable to the Medi-Cal List of Contract Drugs. While all drugs included on the Medi-Cal List of Contract Drugs do not need to be included on the MCOs' PDLs, comparable means that the drugs on the PDLs must have the same mechanism of action sub-class within all major therapeutic categories of drugs included in the Medi-Cal List of Contract Drugs.

Starting in FFY 2018, the DUR Board expanded to become the Global Medi-Cal DUR Board, with MCO representatives now included as Board members. MCOs utilize the Global Medi-Cal DUR Board and educational components of the Medi-Cal DUR program. However, MCOs maintain their current proprietary claims processing procedures and protocols and MCPs individually administer the systematic components related to the prospective and retrospective DUR processes. As is the case with the Fee-For-Service (FFS) program, MCOs are not required to implement all DUR Board recommended actions, nor are they required to mirror the Medi-Cal DUR activities.

If "No," do you plan to set standards in the future?

☐Yes ☐No

4. Did all of your managed care plans submit their DUR reports?

☒Yes ☐No

If “No,” please explain why.

XII. EXECUTIVE SUMMARY - Attachment 8 – Executive Summar

ATTACHMENT 1 – PHARMACY ORAL COUNSELING COMPLIANCE REPORT

Monitoring Pharmacy Compliance with OBRA 1990 DUR Requirements

California pharmacy regulations require pharmacies to maintain patient medication profiles and counsel patients regarding their prescription medication before dispensing. Consultation provides the pharmacist with the opportunity to educate patients who present new prescriptions and protect them from potential problems associated with a new medication by discussing possible side effects, contraindications and the importance of following directions. Consultation also provides the pharmacist one more opportunity to prevent dispensing errors by inspecting the medication container's contents to assure that the proper drug is dispensed.

Compliance to these requirements is the responsibility of the California Department of Consumer Affairs, Board of Pharmacy, which compiles annual reports that are available at: https://www.dca.ca.gov/publications/annual_reports.shtml.

As part of its ongoing activities, the California Board of Pharmacy investigates complaints involving care provided in pharmacies. The California Board of Pharmacy typically will inspect the pharmacy in question at the start of each complaint investigation. Other inspections the Board performs include but are not limited to initial licensure, changes in ownership, change in location or a remodel, or simply a random inspection. A major function of an inspector's activities during these inspections is education of licensees regarding compliance with laws and regulations.

When an inspector, who is a licensed pharmacist, visits a pharmacy to investigate a complaint or inspect a pharmacy, the inspector observes whether patient consultation is occurring and specifically notes the progress and components of the consultations; e.g., the temporal relationship between review of the patient profile and the consultation. Failure to consult or perform prospective drug utilization review prior to consultation results in a "correction ordered" and, possibly, a notice of violation. To ensure compliance, inspectors revisit pharmacies and follow up on correction notices. Violation notices usually result in the pharmacist, pharmacist-in-charge, and pharmacy management meeting with a subcommittee of the Board to discuss the violation.

The above-referenced Board of Pharmacy regulations were determined previously by the Centers for Medicare & Medicaid Services, in order to comply with the prospective DUR requirements of OBRA 90.

A specific report about compliance with oral counseling requirements is not available from the California State Board of Pharmacy. As described by this Board, they typically evaluate compliance whenever a pharmacy is brought to the Board’s attention through issues of fraud or abuse or a complaint of any sort. Verification of oral counseling is contained within these reports (made to various state and federal agencies) and is not separated out.

ATTACHMENT 2 – RETROSPECTIVE DUR EDUCATIONAL OUTREACH SUMMARY

DHCS publishes and distributes Medi-Cal educational bulletins and alerts to all Medi-Cal providers. In addition, providers are identified for education on specific issues based on characteristics of their prescribing and receive intervention letters. Providers who receive an intervention letter are requested to complete and return a survey.

Medi-Cal educational bulletins are available to the public on the Medi-Cal DUR website at: http://files.medi-cal.ca.gov/pubsdoco/dur/edarticles.asp. The purpose of DUR educational bulletins and alerts is to increase Medi-Cal providers' understanding of current treatment guidelines and recommendations on drugs, disease states, and medical conditions. Utilization trends amongst FFS beneficiaries are presented to increase provider awareness. Specific recommendations are made with each article on how to improve the quality of care for Medi-Cal beneficiaries. Recommendations made to Medi-Cal providers through a total of six educational bulletins and alerts distributed during FFY 2018 include the following:

1. Drug Safety Communication: New Age Limit for Opioid Cough and Cold Medicines – February 2018

   Summary: This educational alert reviewed the U.S. Food and Drug Administration (FDA) safety labeling changes for prescription cough and cold medicines containing codeine or hydrocodone, including recommendations that use of these products be limited to adults 18 years of age and older because the risks of these medicines outweigh their benefits in children younger than 18 years of age. The FDA is also requiring the addition of safety information about the risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing to the *Boxed Warning* on drug labels for prescription cough and cold medicines containing codeine or hydrocodone.

   Recommendations:
   1. Health care professionals should be aware that the FDA is changing the age range for which prescription opioid cough and cold medicines are indicated.
   2. Health care professionals should reassure parents that cough due to a cold or upper respiratory infection is self-limited and generally does not need to be treated.

2. In the Pharmacy: Pharmacists Furnishing Nicotine Replacement Products – March 2018

   Summary: This educational bulletin reviewed the California State Board of Pharmacy regulations for pharmacist furnishing of nicotine replacement therapy (NRT), which have been in effect since January 2016. The article also summarizes best practices for responsible prescribing of NRT products and describes strategies to promote smoking cessation in pharmacy practice.

Recommendations:

1. Encourage use of brief interventions (less than 10 minutes) by health care professionals, in order to influence tobacco quit rates.
2. Health care professionals, including pharmacy technicians, should encourage active tobacco users to quit at every encounter.
3. Furnish combination NRT therapy, which has been shown to be more effective at improving quit rates than NRT monotherapy.
4. Recommend both counseling and medication to patients for best results, unless contraindicated or not indicated.
5. All pharmacists should review the California State Board of Pharmacy regulations for pharmacist furnishing of NRT and complete the necessary training in order to furnish NRT.
6. Pharmacists and pharmacy technicians should identify and document current and past tobacco use or other nicotine use as a routine part of patient care, including smokeless tobacco and electronic nicotine delivery systems. If necessary, pharmacy technicians should undergo training to participate in these activities.

3. Drug Safety Communication: Adverse Effects from Fluoroquinolone Antibiotics – July 2018

Summary: This educational alert reviewed the FDA safety labeling changes to strengthen existing warnings for fluoroquinolone antibiotics. Updated labeling will add that low blood sugar levels may lead to coma and will also make mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class.

Recommendations:

1. Health care professionals should be aware of the potential risk of hypoglycemia, which occurs more frequently in the elderly and in those with diabetes taking an oral hypoglycemic medicine or insulin, and counsel patients regarding the signs and symptoms of hypoglycemia, monitor blood glucose levels and discuss self-treatment.
2. Health care professionals should review the risk of psychiatric adverse reactions that may occur after just one dose.
3. Health care professionals should stop fluoroquinolone treatment immediately if a patient reports any central nervous system side effects or serious side effects involving the tendons, muscles, joints, or nerves. In these cases, patients should be switched to a non-fluoroquinolone antibiotic, if possible, to complete the treatment course.
4. Health care professionals should continue to not prescribe fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections, because the risks outweigh the benefits in these patients.

4. ProDUR Update: Additive Toxicity Alert Now Focused Only On CNS Depressants – July 2018

   Summary: This educational bulletin described the drug safety communications by the FDA regarding the combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS). The article also reviewed updates to the additive toxicity (AT) alert in the Medi-Cal fee-for-service prospective drug utilization review (DUR) system. The AT alert is now generated when a patient reaches a threshold of four active prescriptions within the following therapeutic categories: opioids, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with CNS depressant properties.

   Recommendations:
   1. Before prescribing any CNS depressant, health care professionals should assess patient-specific risk factors that may put beneficiaries at a higher-risk for adverse events.
   2. Health care professionals should limit prescribing opioid pain medications with benzodiazepines or other CNS depressants only to patients for whom alternative treatment options are inadequate.
   3. If CNS polypharmacy cannot be avoided, health care professionals should work to limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect.
   4. Patients and caregivers should be advised about the risks of respiratory depression and sedation if opioids are used with benzodiazepines and other CNS depressants, including alcohol and recreational drugs. Naloxone should be discussed with patients and caregivers, and prescribed when indicated.
   5. Pharmacists should review the concomitant prescription data generated by the AT alert with prescribers, especially in cases where beneficiaries have multiple prescribers and/or pharmacies.
   6. Health care professionals should take precautions and develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants.

5. Alert: Mandatory Use of CURES 2.0 Begins October 2, 2018 – September 2018

   Summary: This educational alert describes the upcoming mandatory requirement to consult California's prescription drug monitoring program (CURES 2.0) prior to prescribing, ordering, administering, or furnishing a Schedule II – IV controlled substance, effective on October 2, 2018.

   Recommendations:
   1. Consult the CURES 2.0 database to review a patient's controlled substance history before prescribing a Schedule II – IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient.

6. 2018 Immunization Updates: Flu, Tdap, HepB, Zoster, MMR, Adult Vaccines – September 2018

Summary: This educational bulletin is an annual publication provided by the DUR program to provide updates on immunization guidelines, products, policy and/or research each year. Links to recommended immunization schedules for 2018 in the United States are also provided. The summary for 2018 included updates for influenza, Tdap, HepB, zoster, and MMR. Additionally, an evaluation was presented regarding the frequency of adult vaccine administration in the pharmacy setting.

Recommendations:

1. Advisory Committee on Immunization Practices (ACIP) recommends that as in prior years, routine annual influenza vaccination is recommended for everyone 6 months of age and older without contraindications. Following the past two seasons where live attenuated influenza vaccine (LAIV) was not recommended, LAIV is once more an option for patients who meet the criteria.
2. Pregnant women may receive any licensed, recommended, and age-appropriate influenza vaccine.
3. Pregnant women should receive a Tdap shot at the earliest opportunity between 27 and 36 weeks' gestation of every pregnancy, even if previously immunized.
4. Parents should immunize their babies against pertussis as soon as possible and adults should receive at least one Tdap booster to avoid the spread of pertussis.
5. Health care professionals should review previously published recommendations for the prevention of hepatitis B virus (HBV) infection, which have been recently summarized and consolidated.
6. Health care professionals should consider the use of a recently approved zoster vaccine, recombinant zoster vaccine (RZV), which is now available for immunization of immunocompetent adults 50 years of age or older. RZV is also recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received live zoster vaccine.
7. In light of recent outbreaks of mumps, ACIP now recommends a third dose of a mumps virus-containing vaccine for people previously vaccinated with two doses who are identified by public health authorities as being part of a group or population at increased risk for acquiring mumps because of an outbreak. This third dose may be administered as measles, mumps, and rubella (MMR) vaccine or measles, mumps, rubella, and varicella (MMRV) vaccine.

The Medi-Cal DUR program also sends educational intervention letters to selected providers and pharmacies on certain topics in conjunction with the educational bulletins. The purpose of the educational intervention letters is to improve the quality of care of Medi-Cal beneficiaries. Providers are informed of the goal of each intervention and receive educational materials, along with suggested recommendations for action. A response survey is included with each letter to promote dialogue between the Medi-Cal DUR program and the providers and pharmacies. In FFY 2018, the following three mailings were sent:

1. Triptan Letter – March 2018 and April 2018

   Objectives:
   - To inform providers of the available options for migraine prevention on the Medi-Cal List of Contract Drugs; and
   - To improve the quality of care among Medi-Cal FFS beneficiaries with high use of triptan medications.

   Methods: The study population included fee-for-service beneficiaries that were continuously eligible between January 1, 2017, and December 31, 2017 (the measurement year) and were high users of triptan medications (defined as greater than 12 doses per month, for each month during the measurement year) and had fewer than seven paid claims for migraine preventive medications during the measurement year.

   Outcomes: Only eight patients met the inclusion criteria (a total of 12 prescribers were identified for the mailing). While the letters were mailed on March 13, 2018 (5 letters were re-mailed with updated addresses on April 11, 2018), primary and secondary outcomes were not calculated due to small sample size. Lessons learned from this mailing were discussed with the Board, including how the expansion the definition of a migraine preventive medication to include medications beyond those with the highest levels of evidence for preventing episodic migraines greatly increased the percentage of high users of triptan medications with ≥ 7 preventive medications during the measurement year.

2. Buprenorphine Letter – August 2018

   Objectives:
   - To inform providers that buprenorphine use among Medi-Cal fee-for-service beneficiaries is associated with high adherence rates and decreased concomitant use of high-risk medications, including other opioids
   - To increase the number of Medi-Cal patients receiving treatment with buprenorphine
   - To increase the number of Medi-Cal providers able to provide buprenorphine treatment

   Methods: The top prescribers (by total quantity prescribed) of opioids in the Medi-

Cal fee-for-service program between August 1, 2017 and July 31, 2018 were cross-referenced to the list of California providers with a current waiver to provide buprenorphine treatment. A total of 100 of the top prescribers of opioids without a current buprenorphine waiver were sent a letter with more information about buprenorphine training.

Outcomes: The overall 90-day response rate was 18%. Additional outcomes will be evaluated after the data are complete and will be presented to the DUR Board at that time. The primary outcome variable will be the percentage increase in the number of patients (all of Medi-Cal) with paid claims for buprenorphine among all providers who received the mailing, calculated one year prior to and one year after the mailing. The following secondary outcome variables will also be assessed after one year:

- The number of providers contacted who complete the training and applied for a waiver
- Percentage change (by total quantity prescribed) of total opioid prescribing in the Medi-Cal fee-for-service population, by individual provider among providers contacted.

3. Nicotine Replacement Therapy Letter – August 2018

Objectives:

- To inform pharmacy directors about recent legislation that allows pharmacist reimbursement as providers for selected pharmacy services, including providing tobacco cessation counseling and furnishing NRT
- To encourage pharmacy directors to support their pharmacists in completing the minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy and enrolling as an ordering, referring, and prescribing (ORP) provider in Medi-Cal
- To promote tobacco cessation counseling and furnishing of NRT to eligible Medi- Cal beneficiaries

Methods: Letters were mailed to a total of 172 pharmacies identified as having a practice location in one of the top adult smoking rate counties in California, including Colusa, Del Norte, Fresno, Glenn, Lake, Mariposa, Merced, Shasta, Siskiyou, Stanislaus, Tehama, Trinity, Tulare, Tuolumne, and Yuba. Pharmacies were only mailed a letter if they had paid pharmacy claims for at least 100 Medi-Cal beneficiaries (FFS and MCP beneficiaries were included) during the previous 12 months.

Outcomes: A response rate of 11% was noted within 90 days of the mailing. As stated in the original proposal, the primary outcome will be the number of paid claims for pharmacist-furnished NRT within the 12-month period following the mailing of the intervention letter. Secondary outcomes include the total number of pharmacists in each of the 10 counties successfully completing a DHCS 6219 application (within 12 months of mailing) and the total number of pharmacists in

each of the 10 counties furnishing NRT (within 12 months of mailing). Additional outcomes will be evaluated after the data are complete and will be presented to the DUR Board at that time.

ATTACHMENT 3 – SUMMARY OF DUR BOARD ACTIVITIES

The DUR Board met four times during FFY 2018. The Board members are listed below the summary.

Prospective DUR Criteria Presented

- Ingredient Duplication (ID) Alert – LITHIUM: Lithium was among the top 20 drugs by volume of ingredient duplication (ID) alerts in 2016. An analysis of the ID alerts for lithium found that while the majority of paid claims for lithium (66%) were for the 300 mg immediate-release capsules, only 34% of the ID alerts were generated by this formulation. In addition, almost half (48%) of all paid claims for the immediate-release 150 mg capsules of lithium generated an ID alert. The Board recommended turning off the ID alert for all non-300 mg formulations of lithium. The Board recommended keeping the ID alert on for all 300 mg formulations, as they anticipated there may be cases where the ID alert could be helpful in preventing accidental substitution between 300 mg tablet and 300 mg capsule formulations and/or between 300 mg extended release and 300 mg immediate release formulations.

- Ingredient Duplication (ID) Alert – EMTRICITABINE: When the review of emtricitabine ingredient duplication (ID) alerts was presented at the September 2017 Board meeting the majority of the ID alerts (78%) were due to switch from a regimen containing tenofovir disoproxil fumarate to a regimen containing tenofovir alafenamide. At that time, the Board recommended reviewing these data again in one year to see if regimens had stabilized and the total number of ID alerts had decreased. A review of all ID alerts for emtricitabine between July 1, 2017, and June 30, 2018 was conducted. There were a total of 5,528 ID alerts for emtricitabine during this time period, a decrease of 26% when compared to the prior year. Of note, a spike in ID alerts after the FDA approved a new drug containing emtricitabine, with 23% of all ID alerts for emtricitabine due to patients switching to the new drug from a different drug containing emtricitabine.

- Low Dose (LD) Alert – LITHIUM: The lithium claims generating an ID alert often had other additional alerts present as well, most commonly the low-dose (LD) alert, which was present in 31% of the lithium claims with an ID alert. The LD alert was most commonly generated by the 150 mg and 300 mg immediate-release formulations. Lithium is ranked 1st among all drugs for the greatest volume of LD alerts. The Board recommended turning off the LD alert for lithium.

- Therapeutic Duplication (TD) Alert – ALL DRUGS: During FFY 2018, the Medi-Cal fee-for-service prospective DUR system completed an upgrade to the to include the Duplicate Therapy Module^{TM} from First Databank, Inc. (FDB). As of October 2017, instead of identifying duplicate therapy within only the same drug therapeutic category, this tool compares drug ingredients across multiple, related drug therapeutic categories. Due to the upgrade and ability to review duplicate therapy

across categories, the duplicate therapy categories listed in the DUR manual were determined to be obsolete and the Board recommended this section of the manual be retired.

- Drug-Pregnancy (PG) Alert – ALL DRUGS: The Board had previously recommended an annual review of the PG alert, which was time-consuming and led to discrepancies when the severity level changed for a drug in the interim between the change and the annual review. The Board recommended turning on the PG alert for all drugs (including new GCNs), effective September 2018. There was a precedence for this change with the drug-drug interaction (DD) alert, which has the alert on for all drugs, but alerts are only generated for severity level 1 interactions. An analysis of PG alert volume following the change showed there was no change in the total number of PG alerts generated.

- Therapeutic Duplication (TD) Alert – LEVONORGESTREL: Effective March 6, 2018, the TD alert for all GCNs for levonorgestrel emergency contraception was turned off because paid claims for levonorgestrel emergency contraception were generating TD alerts when submitted at the same time as a claim for contraceptive pills for birth control. The Board did not recommend further action.

- Review of new Generic Code Number (GCN) sequence numbers: The DUR Board recommended turning on additional alerts for the following new GCNs that matched drugs appearing on the Medi-Cal target drug list for prospective DUR:
  1. GCN #077508: KETOPROFEN, MICRONIZED – Drug-Pregnancy (PG)
  2. GCN #077520: GABAPENTIN – Drug Allergy (DA), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  3. GCNs #077479 and #078336: FENTANYL/BUPIVACAINE/NS/PF – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  4. GCN #077612: FENTANYL ROPIVACAINE/NS/PF – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  5. GCNs #077494, #077495, and #077496: METHYLPHENIDATE – High Dose (HD), Low Dose (LD)
  6. GCN #077621: DEXRAZOXANE HCL – Drug-Pregnancy (PG)
  7. GCN #077355: MIDAZOLAM HCL IN 0.9 % NACL – Additive Toxicity (AT) in test mode, Drug-Pregnancy (PG)
  8. GCN #077355: DAUNORUBICIN/CYTARABINE LIPOS – Drug-Pregnancy (PG)
  9. GCNs #075976 and #075977: SIMVASTATIN – Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Ingredient Duplication (ID), Drug-Age (PA), High Dose (HD)
  10. GCNs #077672 and #077673: OLAPARIB – Drug-Pregnancy (PG)
  11. GCN #046605: SPIRONOLACTONE – Drug-Pregnancy (PG)
  12. GCN #077700: GEMTUZUMAB OZOGAMICIN – Drug-Pregnancy (PG)
  13. GCNs #077647 and #077648: BETRIXABAN MALEATE –Late Refill (LR)
  14. GCN #077557: TRIPTORELIN PAMOATE – Drug-Pregnancy (PG)

15. GCNs #077685, #077686, #078185, #078186, and #078187: AMANTADINE HCL – High Dose (HD), Low Dose (LD)
16. GCNs #069014, #070070, #077754, #075653, #078019: HYDROMORPHONE HCL/0.9% NACL/PF – Additive Toxicity (AT) in test mode
17. GCN #077756: MORPHINE SULFATE IN 0.9 % NACL – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
18. GCNs #077491 and #077492: DELAFLOXACIN MEGLUMINE – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
19. GCN #077772: FENTANYL CITRATE-0.9 % NACL/PF – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
20. GCN #077679: TETRACYCLINE HCL – Drug Allergy (DA), Drug-Pregnancy (PG), Therapeutic Duplication (TD), Ingredient Duplication (ID), Ingredient Duplication (ID), Drug-Age (PA), High Dose (HD), Low Dose (LD)
21. GCN #077741: CYCLOBENZAPRINE/TENS UNIT/ELEC – Additive Toxicity (AT) in test mode
22. GCN #077742: CYCLOBENZAPRINE/TENS ELECTRODE – Additive Toxicity (AT) in test mode
23. GCN #077743: THEOPHYLLINE ANHYDROUS – Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
24. GCN #077792: DILTIAZEM HCL IN 0.9% NACL – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
25. GCN #077783: ETANERCEPT – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR)
26. GCNs #069105 and #077951: POTASSIUM CHLORIDE IN 0.9%NACL – Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
27. GCNs #077813, #077814, and #077815: MINOCYCLINE HCL – Drug-Pregnancy (PG)
28. GCNs #077884 and #077989: D-METHORPHAN/PE/ACETAMINOPHEN – Ingredient Duplication (ID), High Dose (HD)
29. GCN #077706: BOSENTAN – Drug-Pregnancy (PG)
30. GCN #077907: TRETINOIN MICROSPHERES – Drug-Pregnancy (PG)
31. GCN #077948: DOLUTEGRAVIR/RILPIVIRINE – Ingredient Duplication (ID)
32. GCN #077827: SODIUM/POTAS/CHLOR/MAGNES/PHOS – Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
33. GCN #074967: MIDAZOLAM HCL IN 0.9 % NACL/PF – Drug-Pregnancy (PG), Additive Toxicity (AT) in test mode
34. GCN #077984: BOSUTINIB – Drug-Pregnancy (PG)
35. GCN #078024: DM/PE/ACETAMINOPH/DIPHENHYDRAM – Ingredient Duplication (ID), High Dose (HD)
36. GCN #078045: NIVOLUMAB – Drug-Pregnancy (PG)

37. GCN #078038: METHYLPHENIDATE HCL – High Dose (HD), Low Dose (LD)
38. GCN #072354: GEMCITABINE HCL – Drug-Pregnancy (PG)
39. GCN #078005: BORTEZOMIB – Drug-Pregnancy (PG)
40. GCN #078062: DAPAGLIFLOZIN/METFORMIN HCL – Drug-Disease (MC), Therapeutic Duplication (TD), High Dose (HD), Low Dose (LD)
41. GCN #078093: APIXABAN – Late Refill (LR)
42. GCN #078091: DIPHENHYD/PE/ACETAMINOPHEN/GG – Ingredient Duplication (ID), High Dose (HD)
43. GCN #078146: BICTEGRAV/EMTRICIT/TENOFOV ALA – Ingredient Duplication (ID)
44. GCNs #078051, #078052, #078053, and #078054: ERTUGLIFLOZIN/METFORMIN – Drug-Disease (MC), Therapeutic Duplication (TD), High Dose (HD), Low Dose (LD)
45. GCNs #078180, #078181, #078182, #078183, and #078192: IBRUTINIB – Drug-Pregnancy (PG)
46. GCN #078147: DICLOFENAC SODIUM/MENTHOL – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
47. GCNs #078145 and #078254: EFAVIRENZ/LAMIVU/TENOFOV DISOP – Drug-Pregnancy (PG), Ingredient Duplication (ID)
48. GCN #078238 and #078498: MITOMYCIN – Drug-Pregnancy (PG)
49. GCN #078252: NILOTINIB HCL – Drug-Pregnancy (PG)
50. GCNs #077567, #077568, and #077569: PITAVASTATIN MAGNESIUM – Drug-Pregnancy (PG) and Late Refill (LR)
51. GCN #078131 and #078139: DIPHENHYDRAM/PE/DM/ACETAMIN/GG – Ingredient Duplication (ID), High Dose (HD)
52. GCN #078224: LAMIVUDINE/TENOFOVIR DISOP FUM – Ingredient Duplication (ID)
53. GCN #078264: PREDNISOLONE ACETATE/BROMFENAC – Drug-Pregnancy (PG)
54. GCN #078286: DUTASTERIDE – Drug-Pregnancy (PG)
55. GCN #078077: LEVONORGEST/ETH.ESTRADIOL/IRON – Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
56. GCN #075279: RITONAVIR – Ingredient Duplication (ID)
57. GCN #027229: BACLOFEN – Additive Toxicity (AT)
58. GCN #068888: MORPHINE SULFATE/0.9% NACL/PF – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
59. GCN #078426: NORTRIPTYLINE HCL – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
60. GCN #078456: MORPHINE SULFATE – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
61. GCN #078461: ABIRATERONE ACET,SUBMICRONIZED – Drug-Pregnancy

(PG)
62. GCNs #078432, #078433, #078034, #078435, and #078036: EPOETIN ALFA-EPBX – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
63. GCN #078481: OMEPRAZOLE – Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
64. GCN #078487: TIMOLOL/DORZOLAMIDE/LATANOP/PF – Drug-Pregnancy (PG)
65. GCN #078488: DORZOLAMIDE/TIMOLOL/PF – Drug-Pregnancy (PG)
66. GCN #078497: TIMOLOL/BRIMONIDIN/DORZOLAM/PF – Drug-Pregnancy (PG)
67. GCN #078505: TIMOLO/BRIMON/DORZO/LATANOP/PF – Drug-Pregnancy (PG)
68. GCN #078532 and #078533: OXYCODONE HCL – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
69. GCN #067584: HYDROXYUREA – Drug-Pregnancy (PG)
70. GCN #078504: TIMOLOL MALEATE/LATANOPROST/PF – Drug-Pregnancy (PG)
71. GCN #078477 and #078477: ESTRADIOL – Drug-Pregnancy (PG), Drug-Disease (MC)

Retrospective DUR Criteria Presented

- Hepatitis C Virus (HCV) Drugs: HCV medication utilization is reviewed on an annual basis, primarily to evaluate potential HCV reinfection and retreatment in the Medi-Cal FFS population. Data showed a 13% decrease in total utilizing beneficiaries with a paid claim for an HCV treatment medication since the previous year, which is similar to the overall decrease in total utilizing beneficiaries in the Medi-Cal FFS program (10%) during this same time period. There was also an increase in beneficiaries with paid claims for both elbasvir/grazoprevir and sofosbuvir/velpatasvir, which is most likely due to these drugs being FDA-approved during the prior year of evaluation (January 2016 and July 2016, respectively). Given that pharmacy and medical claims data continue to show use of these drugs follows updated clinical guidelines, the Board recommended continuing to evaluate utilization data for these drugs on an annual basis, with an expansion to the entire Medi-Cal population during subsequent reviews.

- HIV Antiretroviral Medications: The August 2014 evaluation published by the Office of Inspector General (OIG) that reviewed Medicare Part D claims data for all HIV antiretroviral medications was used as a template to review questionable utilization patterns within the Medi-Cal fee-for-service claims data. Beneficiaries were considered to have questionable utilization patterns if they had extreme results on one or more measures. Pharmacy and claims data were reviewed for all Medi- Cal beneficiaries with at least one paid claim for any HIV antiretroviral medication between January 1, 2017, and December 31, 2017. Results of the analysis showed that across all six measures, less than 1% of Medi-Cal beneficiaries were identified

as having one or more questionable utilization patterns. Among the subset of beneficiaries that were continuously eligible in the Medi-Cal FFS population during 2017, less than 20 beneficiaries in total were identified as having one or more questionable utilization patterns. The Board determined there was no need for further evaluation of these data, but recommended periodic evaluation of the utilization patterns of high-cost drug classes, on an ongoing basis.

- Review of FFS CCS/GHPP Drugs (FFY 2017): A one-year summary of paid pharmacy claims data for beneficiaries enrolled in either the California Children's Services (CCS) Program or the Genetically Handicapped Persons Program (GHPP) was presented. These data were presented in three tables: 1) the top 20 drugs by utilizing beneficiaries, 2) the top 20 drugs by total reimbursement paid to pharmacies, and 3) the top 20 drugs by reimbursement paid to pharmacies per utilizing beneficiary. These data had not been presented previously. The Board made no recommendations for additional follow-up with this population.

- Hypertension Medication Adherence: The methodology used to measure adherence to hypertension medications and evaluate the use of home blood pressure monitoring (HBPM) devices among Medi-Cal beneficiaries was reviewed and adherence to hypertension medication was measured using the proportion of days covered (PDC) method, with a PDC greater than or equal to 80% considered adherent. Pharmacy claims data were evaluated for the calendar year 2017. However, medical claims data were evaluated for a longer time frame (dates of service between January 1, 2012, and December 31, 2017), in order to determine if the frequency of paid claims for HBPM devices has changed over time. Adherence rates were low across all categories, even in comparison to other studies that evaluated adherence to antihypertensive in the Medicaid population. Adherence rates ranged from 19.8% of the study population without an ICD-10 code for hypertension that was using potassium-sparing diuretics to a high of 44.7%, which includes the study population with an ICD-10 code for hypertension that was using angiotensin II receptor blockers (ARBs). Across all drug categories, adherence rates were higher when the beneficiary had a documented ICD-10 code for hypertension. The Board made no recommendations for additional evaluation.

Provider-specific Interventions

Educational articles and alerts:

- Drug Safety Communication: New Age Limit for Opioid Cough and Cold Medicines – February 2018
- In the Pharmacy: Pharmacists Furnishing Nicotine Replacement Products – March 2018
- Drug Safety Communication: Adverse Effects from Fluoroquinolone Antibiotics – July 2018
- ProDUR Update: Additive Toxicity Alert Now Focused Only On CNS Depressants – July 2018
- Alert: Mandatory Use of CURES 2.0 Begins October 2, 2018 – September 2018

- 2018 Immunization Updates: Flu, Tdap, HepB, Zoster, MMR, Adult Vaccines – September 2018

Provider intervention letters:

- Buprenorphine Letter – August 2018
- NRT Letter – August 2018
- Triptan Letter – March 2018 and April 2018

Ongoing DUR Board Projects

The DUR Board goals for FFY 2018 were as follows:

- Implement the DUR requirements of Medicaid and CHIP Managed Care Final Rule (CMS-2390-F)
- Implement the APL 17-008
- Revise the Global DUR Bylaws
- Promote dialogue, collaboration and recommend best practices in pharmacy utilization management on drugs commonly used in both Medi-Cal fee-for-service (FFS) and managed care plans (MCPs)
- Establish a plan to systematically review prospective DUR alerts
- Establish a plan to systematically develop retroactive DUR criteria
- Conduct learning collaborative with MCOs and other agencies to promote best practices using academic detailing (AD)
- Align DUR board goals with DHCS Quality Strategy

The following are ongoing DUR Board projects:

- Morphine Equivalent Daily Dose (MEDD) – The DUR Board continues to collaborate with other State agencies, including the California Medical Board, the Division of Worker's Compensation, and the State Board of Pharmacy to develop a cohesive policy regarding opioids, MEDD, and prescription drug abuse.
- Automatic Refill Policy – The Board is considering a requirement that would allow pharmacies to automatically refill prescriptions only upon a patient's consent or request. The Board is currently discussing the policy recommendation that they will provide to DHCS.

DUR Board Members

The following members served on the DUR Board, either in part or for the entire duration, of FFY 2018:

Member	Specialty/Affiliation
Timothy E. Albertson, M.D., M.P.H., Ph.D.	Chair, Department of Internal Medicine, Division of Pulmonary and Critical Care Medicine and Professor of Medicine and Pharmacology, UC Davis Medical Center, Sacramento, California
Michael Blatt, Pharm.D.	Pharmacy Director, Central California Alliance for Health
Chris Chan, Pharm.D.	Independent Pharmacy Consultant
Lakshmi Dhanvanthari, M.D.	Chief Medical Officer, Health Plan of San Joaquin
José Dryjanski, M.D.	Regional Chair Infectious Disease SCPMG and Regional Chair P & T SCPMG, Chief Infectious Disease Kaiser Woodland Hills
Stan Leung, Pharm.D.	Director, Pharmacy Services. Partnership HealthPlan of California
Johanna Liu, Pharm.D., MBA, FCPhA	Director of Quality & Pharmacy, Santa Clara Family Health Plan, San Jose, California
Janeen McBride, Pharm.D.	Principal, Government Programs, MedImpact Healthcare Systems, Inc., San Diego, California
Robert Mowers, Pharm.D.	Coordinator Managed Care Pharmacy Services, Department of Pharmacy Services, UC Davis Health System, Sacramento, California
Yana Paulson, Pharm.D.	Chief Pharmacy Officer, L.A. Care Health Plan, Adjunct Assistant Professor, UOP School of Pharmacy
Randall S. Stafford, M.D., Ph.D.	Director, Program on Prevention Outcomes and Practices, Stanford Prevention Research Center, and Professor of Medicine, Stanford University School of Medicine, Palo Alto, California
Marilyn Stebbins, Pharm.D.	Professor of Clinical Pharmacy, UCSF School of Pharmacy, San Francisco, California
Vic Walker, R.Ph.	Former DUR pharmacist and head of the Pharmacy Data Analysis Group, California Department of Healthcare Services
Andrew L. Wong, M.D.	Chief of Rheumatology, Olive View-UCLA Medical Center, Sylmar, California Professor of Clinical Medicine, David Geffen School of Medicine at UCLA, Los Angeles, California
Iris Young, Pharm.D., CPHQ	Director, Pharmacy Quality and Medication Safety & PGY2 Medication Use Safety Program, Kaiser Permanente, Northern California Regional Pharmacy Operations & National Pharmacy Programs and Services
Ramiro Zuniga, M.D., MBA, AAFP	Medical Director, California Health & Wellness, Health Net of California and Associate Clinical Professor Department of Family and Community Medicine (VCF), UC Davis School of Medicine, Sacramento, California

ATTACHMENT 4 - GENERIC DRUG SUBSTITUTION POLICIES

Among possible factors contributing to the Medi-Cal fee-for-service generic utilization percentage, the most impactful are the following: 1) supplemental rebate contracts with manufacturers; 2) carve-out drugs; and 3) generic drug pricing policies.

1) Restrictions to the Medi-Cal List of Contract Drugs

The Medi-Cal Drug Rebate program negotiates supplemental rebate contracts with pharmaceutical manufacturers and collects rebates greater than rebates obtainable through federal contracts alone. As a result, the net cost to the State for some brand name drugs can be lower than the therapeutically equivalent generic drug. In some cases, contracted drugs are payable at the point of service, while their generic equivalents require prior authorization. On the Medi-Cal List of Contract Drugs, these drugs can be identified through restrictions to the NDC labeler code. The current Medi-Cal List of Contract Drugs is available here:
http://files.medi-cal.ca.gov/pubsdoco/manual/man_query.asp?wSearch=%28%23filename+drugscdl%2A%2Edoc+OR+%23filename+drugscdl%2A%2Ezip%29&wFLogo=Contract+Drugs+List&wFLogoH=52&wFLogoW=516&wAlt=Contract+Drugs+List&wPath=N.

2) Carve-out Pharmacy Benefits

The Medi-Cal fee-for-service program pays for certain carved-out therapeutic classes of drugs for beneficiaries in both the Medi-Cal fee-for-service program and the Medi-Cal managed care program. Most notably, this applies to selected psychiatric drugs, alcohol and heroin detoxification and dependency treatment drugs, coagulation factors, and drugs used in treatment of Human Immunodeficiency Virus (HIV) and AIDS. These classes of drugs are largely single-source innovator products and consistently account for a large portion of Medi-Cal drug benefit expenditures in the Medi-Cal fee-for-service population. For a complete description of the carved-out drugs, please see:
https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part1/mcptwoplan_z01.doc.

3) Policies encouraging generic equivalent substitution for drugs dispensed through the Medi-Cal program.

In cases where generic drugs are more cost-effective, Medi-Cal encourages use of generic drugs. The providers, to the extent permitted by law, shall dispense the lowest cost drug product within the generic drug type in stock, which meets the medical needs of the beneficiary.

California Business and Professions Code Section 4073 states:

(a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal

Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

The following policies affect generic utilization rate by establishing reimbursement rates for drugs dispensed through the Medi-Cal program:

Reimbursement for any legend and non-legend drug covered under the Medi- Cal program is the lowest of:

- Maximum Allowable Ingredient Cost (MAIC) plus current professional fee
- Federal Upper Limit (FUL) plus current professional fees
- Estimated Acquisition Cost (EAC) plus current professional fees
- Charge to the general public

Among these, whenever available, MAIC* and FUL** promote the use of generic equivalents unless restricted on the Contract Drug List. The rates established by MAIC or FUL are generally much lower than the cost of branded products, which discourages providers from filling prescriptions with name brand drugs. Full reimbursement of prescription ingredient cost requires use of a brand of a multiple source drug, which costs no more than the program specified price limits. When medically necessary for a specific recipient, approval of reimbursement may be obtained for a product whose price exceeds the MAIC or FUL price limits by requesting authorization from a Medi-Cal consultant.

***The Maximum Allowable Ingredient Cost (MAIC**)
The Maximum Allowable Ingredient Cost (MAIC) program establishes maximum ingredient cost limits for generically equivalent drugs. Each cost limit is established only when there are three or more generically equivalent drugs available for purchase and dispensing by retail pharmacies within California.

****Federal Upper Limit (FUL)**
Federal Upper Limit (FUL) is an upper-limit of reimbursement for certain multiple source drugs established independently from the California MAIC Program by the United States Department of Health and Human Services (DHHS).

The federally required FUL is administered by the Medi-Cal program in a similar manner as the MAIC program. The major difference is that changes to the FUL list of drugs and respective price limits are issued periodically by DHHS and then implemented by Medi-Cal. When a drug is listed on both the MAIC and FUL price lists, the reimbursement rate is the lower of the MAIC or FUL.

ATTACHMENT 5 – COST SAVINGS/COST AVOIDANCE METHODOLOGY

Prospective DUR alerts and educational bulletins provide health care providers and pharmacists with specific, focused, and comprehensive drug information. If DUR alerts and educational bulletins are reviewed as intended, then notification of a potential drug therapy problem through a DUR alert or the knowledge gained from educational bulletins will lead to appropriate action, including:

- Discontinuing unnecessary prescriptions
- Reducing quantities of medications prescribed
- Switching to safer drug therapies
- Adding a drug therapy recommended in evidence-based guidelines
- Appropriate monitoring of patients taking prescription drugs

The Medi-Cal DUR program has saved money by encouraging appropriate drug therapy in order to reduce total healthcare expenditures. Estimated prescription drug savings as a direct result of the prospective DUR system for the FFY 2018 are shown in Table 1.

Table 1. Prospective DUR Cost-Savings for Federal Fiscal Year (FFY) 2018.

Prospective DUR alert	Total claims cancelled or not overriden[1]	Average reimbursement dollars paid to pharmacies per claim[2]	Multiplier[3]	Total estimated costs avoided through prospective DUR
Over Utilization (Early Refill)	751,190	$488	0.10	$36,626,255
Therapeutic Duplication	310,586	$348	0.80	$86,539,292
Under Utilization (Late Refill)	201,712	$325	0.80	$52,512,305
Ingredient Duplication	103,168	$367	0.80	$30,264,130
High Dose	67,359	$104	0.80	$5,590,572
Low Dose	28,376	$110	0.80	$2,495,431
Drug-Pregnancy	26,615	$33	0.80	$695,552
Additive Toxicity	23,446	$161	0.80	$3,021,442
Drug-Drug Interaction	7,166	$1,041	0.80	$5,970,265
Drug-Disease Contraindication	2,859	$87	0.80	$198,046
Drug Allergy	323	$70	0.80	$18,117
Drug Age	272	$199	0.80	$43,233
TOTAL: All Alerts	***1,523,072***	***$349***		***$223,974,640***

[1]Multiple alerts can be generated per claim, so there may be duplicate alerts cancelled or overridden.
[2]Average reimbursement dollars paid to pharmacies per claim was calculated for each alert by looking at the total number of paid claims (including overrides) and total reimbursement dollars paid to pharmacies per claim (does not include adjustment for any rebates) for all drugs that generated that particular alert in FFY 2018.
[3]The use of this multiplier allows for an adjustment of estimated costs using a conservative estimate that 90% of early refill claims are resubmitted and paid and that 20% of the remaining alerts are duplicate alerts for the same claim.

ATTACHMENT 6 – INNOVATIVE PRACTICES

The Medi-Cal DUR Program plays an integral role in the Department of Health Care Services' Strategy for Quality Improvement in Healthcare initiative. The following areas aimed to improve patient safety are linked to the activities of the DUR Program:

1. **Prescription drug overdose** – DHCS continues to collaborate statewide to prevent prescription drug overdose, including with the state's Prescription Drug Overdose Prevention Initiative. The overarching strategy for this initiative includes safe prescribing, access to treatment, naloxone distribution, a public education campaign, and data informed and driven interventions. The goals of the initiative include increasing the number of active buprenorphine prescribers, increasing the number of naloxone claims, decreasing all-cause overdose mortality, reducing the concomitant use of benzodiazepines and opioids, and reducing opioid claims > 90 mg MEDD.

   Initiative activities in FFY 2018 include the development and maintenance of the California Opioid Overdose Surveillance Dashboard, the result of an ongoing collaboration between numerous state agencies. The goal is to provide a data tool with enhanced data visualization and integration of statewide and geographically-specific non-fatal and fatal opioid-involved overdose and opioid prescription data. These dashboards will enable surveillance of several short and long-term goals currently targeted by California's Prescription Drug Overdose Prevention program. Data in the dashboards are maintained and updated at least monthly.

   The Medi-Cal DUR Program also continued to collaborate with the California State Board of Pharmacy and their Prescription Abuse Subcommittee in their mission to:
   - promote the prevention and treatment of prescription drug abuse, particularly the abuse of controlled substances
   - provide education to practitioners and the public regarding prescription drug misuse
   - optimize the widespread use of tools such as Controlled Substance Utilization Review and Evaluation System (CURES)

   Both independently and in collaboration, the DUR Board continues to evaluate opioid pharmacy claims data in order to: 1) characterize the nature and magnitude of opioid use in the Medi-Cal fee-for-service population and 2) develop effective policies and programs to reduce the adverse impact of opioid abuse. For example, after the success of a DUR educational outreach letter to providers, the DUR Board approved a plan to send out an additional mailing to providers that included information about buprenorphine to the top prescribers of opioids (by total quantity prescribed) in the Medi-Cal program.

   In order to address polypharmacy of CNS depressants, the DUR Board also recommended that the additive toxicity (AT) alert be updated to reflect only additive toxicity effects from multiple CNS depressants, including opioids, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine),

antipsychotic medications, and other selected psychotropic medications with CNS depressant properties. In FFY 2018, an educational bulletin on this topic was sent to all Medi-Cal providers and a proposal was approved for a follow-up educational outreach letter to prescribers of Medi-Cal beneficiaries that generated AT alerts due to concomitant use of opioids, benzodiazepines, and two additional CNS depressants.

2. **Development of a companion guide/FAQ for the FFY 2018 DUR Annual Report to CMS** – DHCS worked with the DUR Board to develop the *Medicaid Managed Care Organization Drug Utilization Review Annual Report Companion Guide*, which was designed to provide guidance and assistance to Medi-Cal managed care plans (MCPs) in completing their FFY 2018 annual report. The plan is for these documents to continue to evolve as MCPs begin to work on their reports, updating the FAQ section located at the end of the guide as questions arise.

3. **Academic Detailing** – The 2nd Annual Academic Detailing Conference was held in Sacramento on October 12, 2017. A pre-meeting survey revealed a wide range of academic detailing experience among the conference participants and helped conference organizers to identify key barriers, challenges, and opportunities. Kevin Goddard, a training officer from the Strategic Planning and Workforce Development Branch at DHCS, helped facilitate the consensus workshop process used during the conference. There continues to be overwhelming support and enthusiasm for academic detailing training opportunities. Planning efforts for the 3rd Annual Academic Detailing Conference are ongoing.

4. **Tobacco Control** – The DUR educational bulletin on pharmacist furnishing of nicotine replacement therapy was presented at a meeting of the California Department of Public Health, Tobacco Control Branch. There was great interest by the Tobacco Control Branch in collaborating with the DUR program in order to work with both Medi-Cal fee-for-service and MCPs to streamline formularies for smoking cessation medications and improve the rates of pharmacist furnishing of NRT. The DUR Program learned of future funding available through the Tobacco Control Branch for pharmacies to apply for in order to support training of pharmacists to furnish NRT.

ATTACHMENT 8 – EXECUTIVE SUMMARY

The purpose of Drug Utilization Review (DUR) is to improve the quality and cost-effectiveness of drug use by ensuring that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results. California's Medi-Cal DUR program is the responsibility of the Department of Health Care Services (DHCS), and includes prospective DUR reviews, retrospective DUR reviews, and educational interventions for providers and pharmacies.

During federal fiscal year (FFY) 2018, California's Medi-Cal DUR program expanded to become the Global Medi-Cal DUR Board (the "Board"), which comprises ten pharmacists and six physicians, meeting OBRA 1990 requirements. The Board held four meetings in FFY 2018, with each meeting divided up into two distinct sections: 1) old business and follow-ups; and 2) new business that included placeholders for updates from DHCS and the DUR Board, drug utilization reports, prospective and retrospective DUR reviews, and descriptions of educational bulletins and/or alerts.

The Board is responsible for advising and making recommendations to DHCS for the Medi-Cal population. For FFY 2018 the Board advised and made recommendations for: 1) prospective DUR criteria review and evaluation; 2) focused retrospective analyses of claims data in order to study drug use in the Medi-Cal population; and 3) the development and implementation of educational interventions to improve drug use in the Medi-Cal population.

Over the course of FFY 2018, the Board reviewed prospective DUR criteria for 71 drugs and comprehensively reviewed the status of all drugs for drug-pregnancy (PG) alerts, as well as ingredient duplication (ID) alerts for lithium and emtricitabine, and therapeutic duplication (TD) alerts for levonorgestrel. In addition, retrospective DUR criteria for three drug therapeutic categories were reviewed, as well as all medications that became available on the Medi-Cal Contract Drugs List in FFY 2017. A total of six educational bulletins and alerts were published on the Medi-Cal website in order to educate and inform Medi-Cal providers and beneficiaries on timely and relevant topics related to medication use. A total of two educational mailings were sent to selected prescribers to improve the quality of care for Medi-Cal beneficiaries, and one educational letter was sent to pharmacies to promote pharmacist furnishing of nicotine replacement therapy. Finally, in FFY 2018, the Board continued to collaborate with key state agencies and national experts, expanded the Board membership to include representation from Medi-Cal managed care plans (MCPs), and held the second annual academic detailing conference at DHCS.

This Annual Report was prepared through a collaborative effort between the California Department of Health Care Services, the Global Medi-Cal Drug Use Review Board, Conduent, and the University of California, San Francisco.

TABLE 1 – TOP DRUG CLAIMS DATA REVIEWED BY THE DUR BOARD

Top 10 PA Requests by Drug Name	Top 10 PA Requests by Drug Class	Top 5 Claim Denial Reasons (i.e. QL, Early Refill, PA, Duplication)	Top 10 Drug Names by Amount Paid	% of Total Spent for Drugs by Amount Paid	Top 10 Drug Names by Claim Count	Drugs By Claim Count % of Total Claims
ARIPIPRAZOLE	SECOND GENERATION ANTI-PSYCHOTICS	Claim requires an approved Treatment Authorization Request (TAR) due to beneficiary age	ARIPIPRAZOLE	12.3%	QUETIAPINE FUMARATE	5.1%
PALIPERIDONE PALMITATE	OPIOID ANALGESIC COMBINATIONS AND OPIOID ANALGESICS	Claim requires an approved TAR due to exceeding quantity limits, days supply, and/or frequency	LURASIDONE HCL	5.9%	ARIPIPRAZOLE	3.8%
RISPERIDONE	FIRST GENERATION ANTI-PSYCHOTICS	Claim requires an approved TAR because claim exceeds the 6 prescription limit	PALIPERIDONE PALMITATE	4.6%	RISPERIDONE	3.0%
QUETIAPINE FUMARATE	ANTIHYPER-KINETICS/CNS STIMULANTS	Claim requires an approved TAR because beneficiary does not have the appropriate documented diagnosis on file for this drug	ELVITEG/COB/ EMTRI/TENOF ALAFEN	4.5%	IBUPROFEN	3.0%
HYDROCODONE/ ACETAMINOPHEN	ANTI-CONVULSANTS	Duplicate claim	ABACAVIR/ DOLUTEGRAVI R/LAMIVUDI	3.5%	OLANZAPINE	2.9%
HALOPERIDOL	BENZO-DIAZEPINES	XXXXXXX	COAGULATION FACTOR VIIA,RECOMB	3.3%	BENZTROPINE MESYLATE	2.0%
OLANZAPINE	ANTI-DEPRESSANTS	XXXXXXX	ANTIHEMOPHIL. FVIII,FULL LENGTH	3.2%	ASPIRIN	2.0%
METHYL-PHENIDATE HCL	NARCOTIC ANTAGONISTS	XXXXXXX	EMTRICITABINE /TENOFOVIR (TDF)	2.5%	ALBUTEROL SULFATE	1.7%
BREXPIPRAZOLE	INSULIN	XXXXXXX	EMTRICITABINE /TENOFOV ALAFENAM	2.2%	LORATADINE	1.5%
LITHIUM	PROTON PUMP INHIBITORS	XXXXXXX	DOLUTEGRAVI R SODIUM	2.0%	METFORMIN HCL	1.5%

TABLE 2 - GENERIC UTILIZATION DATA

Single-Source (S) Drugs		Non-Innovator (N) Drugs		Innovator Multi-Source (I) Drugs	
Total Number of Claims	Total Reimbursement Amount Less Co-Pay	Total Number of Claims	Total Reimbursement Amount Less Co-Pay	Total Number of Claims	Total Reimbursement Amount Less Co-Pay
1,703,731	$2,766,806,174	7,598,080	$266,496,188	957,215	$619,150,812

KEY:
Single-Source (S) - Drugs that have an FDA New Drug Application (NDA) approval for which there are no generic alternatives available on the market.

Non-Innovator Multiple-Source (N) - Drugs that have an FDA Abbreviated New Drug Application (ANDA) approval and for which there exists generic alternatives on the market.

Innovator Multiple-Source (I) - Drugs which have an NDA and no longer have patent exclusivity.

UCSF School of Pharmacy

FFY 2018 DUR Annual Report to CMS: Additional Data

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Department of Clinical Pharmacy

FFS Pharmacy Utilization by Age Group

Table 1: Medi-Cal FFS Pharmacy Utilization by Age Group - FFY 2018

Age Group	Total Paid Claims	% Change from FFY 2017	Total Utilizing Beneficiaries	% Change from FFY 2017
0 - 12	1,213,919	-9.7%	272,774	-13.8%
13 - 18	728,207	-2.8%	110,623	-4.0%
19 - 39	3,275,192	-0.3%	685,669	-1.6%
40 - 64	4,498,220	-2.5%	656,257	-1.4%
65+	836,993	-9.3%	155,952	-12.1%
Total	**10,950,377**	-3.9%	**2,032,268**	-5.9%

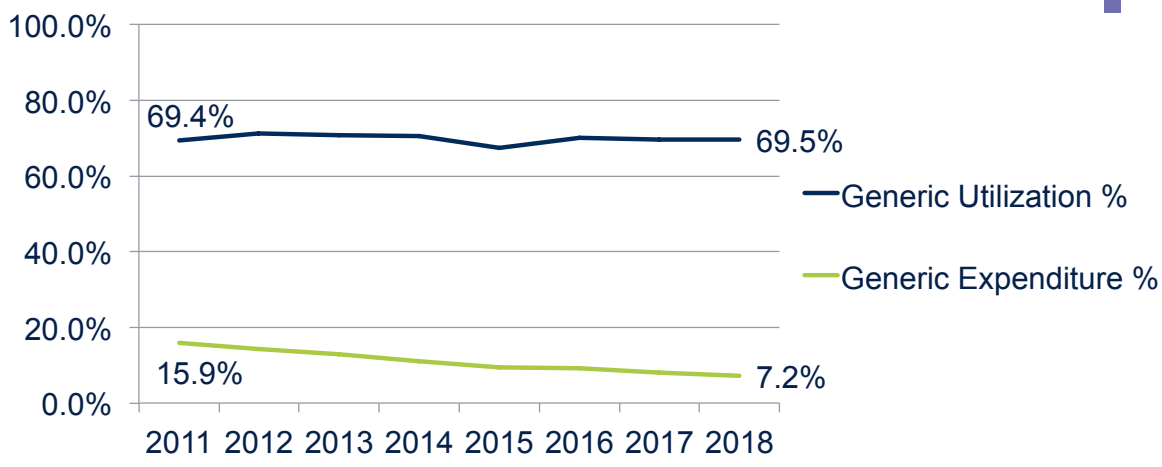
Top 20 Drug Therapeutic Categories

Rank	Drug Therapeutic Category Description	Total Paid Claims	% Change from FFY 2017	Total Utilizing Beneficiaries	% Change from FFY 2017
1	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	402,446	-4.1%	291,658	-4.7%
2	ANTIPSYCHOTIC,ATYPICAL,DOPAMINE,SEROTONIN ANTAGNST	1,622,246	0.4%	207,242	0.5%
3	PENICILLIN ANTIBIOTICS	212,505	-6.3%	170,814	-6.7%
4	CONTRACEPTIVES,ORAL	330,107	-9.3%	140,954	-10.9%
5	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	174,428	-20.0%	124,251	-18.2%
6	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	184,290	-4.5%	96,219	-6.7%
7	CEPHALOSPORIN ANTIBIOTICS - 1ST GENERATION	100,698	-3.3%	88,724	-3.1%
8	IRON REPLACEMENT	161,086	-6.2%	85,155	-10.8%
9	LAXATIVES AND CATHARTICS	185,789	-11.4%	81,326	-13.2%
10	MACROLIDE ANTIBIOTICS	98,211	-12.7%	77,835	-12.8%
11	ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	430,868	2.7%	76,519	2.4%
12	PLATELET AGGREGATION INHIBITORS	224,699	-15.3%	72,081	-15.1%
13	ANTIHISTAMINES - 2ND GENERATION	172,482	-8.8%	70,776	-10.3%
14	ANTICONVULSANTS	350,205	-1.7%	69,995	-0.8%
15	ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	178,261	1.7%	67,786	0.4%
16	TOPICAL ANTI-INFLAMMATORY STEROIDAL	94,303	-10.1%	66,099	-10.5%
17	PRENATAL VITAMIN PREPARATIONS	98,033	-8.5%	65,889	-10.7%
18	ANTIHYPERTENSIVES, ACE INHIBITORS	178,235	-3.7%	65,152	-5.1%
19	GLUCOCORTICOIDS	103,046	-4.3%	64,761	-4.9%
20	ANTIEMETIC/ANTIVERTIGO AGENTS	93,677	-4.6%	64,260	-1.8%

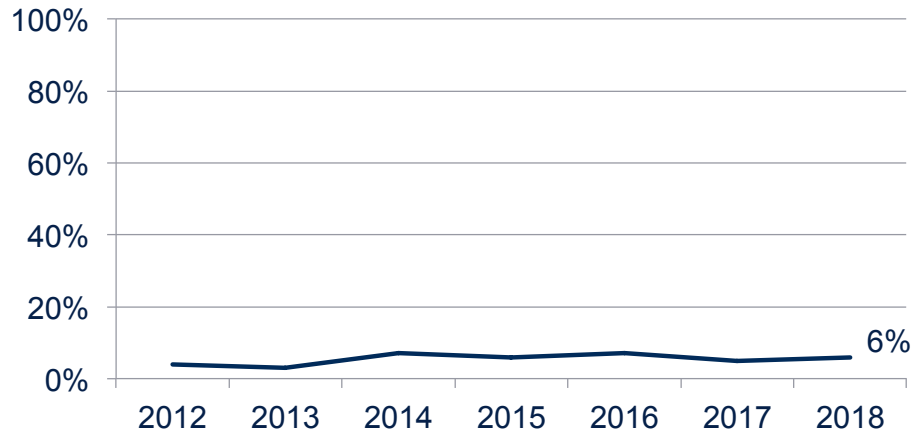
Top 20 Drugs

Rank	Drug Description	Total Paid Claims	% Change from FFY 2017	Total Utilizing Beneficiaries	% Change from FFY 2017
1	IBUPROFEN	328,851	-4.2%	253,749	-4.7%
2	AMOXICILLIN	149,756	-7.7%	124,771	-7.9%
3	ALBUTEROL SULFATE	181,515	-5.4%	98,434	-7.7%
4	HYDROCODONE/ACETAMINOPHEN	123,555	-18.3%	91,711	-16.8%
5	CEPHALEXIN	100,414	-3.3%	88,633	-3.1%
6	QUETIAPINE FUMARATE	553,810	-0.2%	86,202	-0.5%
7	FERROUS SULFATE	160,665	-6.2%	85,066	-10.8%
8	DOCUSATE SODIUM	161,945	-12.2%	74,924	-13.9%
9	ARIPIPRAZOLE	410,886	1.4%	74,021	1.5%
10	AZITHROMYCIN	85,615	-13.7%	72,465	-13.3%
11	ASPIRIN	217,172	-17.5%	70,406	-17.0%
12	LORATADINE	167,186	-9.1%	69,826	-10.5%
13	METRONIDAZOLE	72,816	-5.5%	62,693	-5.7%
14	METFORMIN HCL	163,114	-0.2%	60,228	-1.7%
15	ACETAMINOPHEN	72,249	-19.1%	60,053	-18.8%
16	RISPERIDONE	330,713	-3.0%	53,728	-1.7%
17	OLANZAPINE	311,791	3.4%	50,819	4.4%
18	LISINOPRIL	129,530	-1.4%	50,716	-1.7%
19	SULFAMETHOXAZOLE/TRIMETHOPRIM	65,716	-9.3%	49,264	-10.1%
20	ONDANSETRON HCL	60,986	-2.7%	47,414	0.9%

Trends: Generics



Trends: DUR Cost-Savings Estimate



Board recommendations?

UCSF School of Pharmacy

Retrospective DUR Updates: Q4 2018

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Retrospective DUR Updates – Q4 2018

Topic for Discussion

- Global Quarterly Report: 2Q2018 (April – June 2018)
- FFS Quarterly Report: 4Q2018 (October – December 2018)
- Biennial Report 2018: Part I

Global Quarterly Report: 2Q2018

- First report to include all Medi-Cal pharmacy utilization
- Global report is two quarters behind FFS report
- Will run same data reports again the next two quarters to get better idea on data completeness
  - Will report back to the Board
- Tables 3 and 5 represent global top 20
- Tables 4 and 6 include percentage of total paid claims for FFS vs. MCP enrollees for the global top 20

Global Quarterly Report: 2Q2018

- Among all Medi-Cal beneficiaires with a paid pharmacy claim
  - Approximately 10% were FFS enrollees
  - Approximately 90% were MCP enrollees
- MCP enrollees have a greater average number of paid pharmacy claims per eligible beneficiary (1.94 vs. 0.53)
- MCP enrollees have a greater average number of paid pharmacy claims per utilizing beneficiary (5.75 vs. 3.59),

Global Quarterly Report: 2Q2018

- MCP enrollees had a greater % paid claims for:
  - OMEPRAZOLE, FLUTICASONE PROPIONATE, CHOLECALCIFEROL (VITAMIN D), and BLOOD SUGAR DIAGNOSTIC
- FFS enrollees had a greater % of paid claims for:
  - IBUPROFEN, ASPIRIN, HYDROCODONE/ACETAMINOPHEN, CEPHALEXIN, and FERROUS SULFATE

Board recommendations?

FFS Quarterly Report: 4Q2018

- ProDUR data shows impact of turning ID alert back on for QUETIAPINE (effective December 6, 2018)
- MCP population shows large increases from 2017 for BUPRENORPHINE HCL/NALOXONE HCL (27% increase in utilizing beneficiaries) and NALOXONE HCL (252% increase)
  - FFS enrollee utilization increased too, but less than MCP
- BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE
  - Approved in 2018 and entered top 20 in 2018 Q4 for MCP

Board recommendations?

Biennial Report 2018: Part I

- DUR educational articles are reviewed again at least 2 years after publication to evaluate any change over time
- The 2018 biennial report provides detailed evaluations of 16 DUR educational articles published between October 2014 and September 2016
- Being presented in 2 parts (eight articles each)
  - Part I being presented today
  - Part II will be presented at the May 2019 meeting

Board recommendations?

Future Topics: Retrospective Reviews

- Annual review of drugs added to the Medi-Cal List of Contract Drugs (ongoing, presented each November)
- HCV medications (ongoing, presented each November)
- Pharmacist furnishing of hormonal contraceptives
- Assessment of opioid use and mortality (stratified by gender)
- Topics from today's meeting: Biennial Report, Gabapentin

Future Topics: Adult Core Set Measures

- 2019 Adult Core Set Measures:
  - Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications (SSD-AD)
  - Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD)
  - Adherence to Antipsychotic Medications for Individuals with Schizophrenia (SAA-AD)
  - Concurrent Use of Opioids and Benzodiazepines (COB-AD)
  - Contraceptive Care – Postpartum Women Ages 21–44 (CCP-AD)

Future Topics: Child Core Set Measures

- 2019 Child Core Set Measures:
  - Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication (ADD-CH)
  - Asthma Medication Ratio: Ages 5–18 (AMR-CH)
  - Contraceptive Care – Postpartum Women Ages 15–20 (CCP-CH)

Board recommendations?

QUARTERLY SUMMARY
GLOBAL MEDI-CAL DRUG USE REVIEW
REPORT PERIOD: 2ND QUARTER 2018 (APRIL – JUNE 2018)

Executive Summary

The Global DUR quarterly report provides information on retrospective drug utilization for all pharmacy claims processed by Medi-Cal. For this report, the retrospective data cover the second quarter of 2018 (2018 Q2).

Table 1 provides a summary of pharmacy utilization during 2018 Q2 in the Medi-Cal program, as well as utilization by beneficiaries enrolled in Medi-Cal fee-for-service (FFS) and Medi-Cal managed care plans (MCPs). In 2018 Q2, approximately 15% of eligible Medi-Cal FFS enrollees had a paid pharmacy claim, compared with 34% of Medi-Cal MCP enrollees. Beneficiaries may have enrollments in both Medi-Cal fee-for-service FFS and MCP during a quarter, and therefore may be counted twice in **Table 1**. Among all Medi-Cal beneficiaires with a paid pharmacy claim through the Medi-Cal program in 2018 Q2, only 9.8% were FFS enrollees and 90.8% were MCP enrollees (numbers add up to more than 100% due to < 1% of beneficiairies being enrolled in both programs during 2018 Q3).

FFS enrollees represent approximately 20% of eligible Medi-Cal beneficiaries, 9.8% of utilizing beneficiaires, and 6.3% of total paid pharmacy claims. For 2018 Q2, the MCP enrollees have a higher average number of paid pharmacy claims per eligible beneficiary than the FFS enrollees (1.94 vs. 0.53) and a higher average number of paid pharmacy claims per utilizing beneficiary (5.75 vs. 3.59), which may h MCP enrollees elp explain the higher percentage of paid pharmacy claims by MCP enrollees.

As shown in **Table 2**, pharmacy utilization among all age groups decreased from the prior quarter (2018 Q1), with a 5.5% decrease in total paid pharmacy claims and a 7.6% decrease in total utilizing beneficiaries in comparison to the prior quarter. These data will be reviewed again next quarter, in order to determine if the decrease is due to a lag in claim processing time or reflects a true decrease in utilization due to seasonal trends.

In this quarterly report, two tables highlight utilization among the top 20 drug therapeutic drug categories (**Table 3**) and top 20 drugs (**Table 5**) among all Medi-Cal beneficiaries, in comparision to both the prior quarter and the prior-year quarter (2017 Q2). Two other tables show the top 20 drug therapeutic drug categories (**Table 4**) and top 20 drugs (**Table 6**) along with the percentages of these pharmacy claims that come from FFS and MCP enrollees.

Table 4 suggests a higher percentage of MCP enrollees had paid claims for VITAMIN D PREPARATIONS, NASAL ANTI-INFLAMMATORY STEROIDS, and PROTON-PUMP INHIBITORS than FFS enrollees, while a higher percentage of FFS enrolles had paid claims for PLATELET AGGREGATION INHIBITORS, OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS, and LAXATIVES AND CATHARTICS than MCP enrollees. Similarly, **Table 6** suggests a higher percentage of MCP enrollees had paid claims for OMEPRAZOLE, FLUTICASONE PROPIONATE, CHOLECALCIFEROL (VITAMIN D), and BLOOD SUGAR DIAGNOSTIC than FFS enrollees, while a higher percentage of FFS enrolles had paid claims for IBUPROFEN, ASPIRIN, HYDROCODONE/ACETAMINOPHEN, CEPHALEXIN, and FERROUS SULFATE than MCP enrollees.

Table 1. Summary of Global Medi-Cal Pharmacy Utilization.

This table shows pharmacy utilization in the Medi-Cal program, including the percent change from the prior quarter and prior-year quarter. Beneficiaries with enrollments in both FFS and MCP during the quarter may be counted twice (represents ≤ 1% of utilizing beneficiaries).

Table 1: Pharmacy Utilization Measures for the Entire Medi-Cal Population					
Category	**Current Quarter 2018 Q2**	**Prior Quarter 2018 Q1**	**Prior-Year Quarter 2017 Q2**	**% Change from *Prior Quarter***	**% Change from *Prior-Year Quarter***
Total Eligible Beneficiaries	15,669,240	15,809,161	15,957,384	**-0.9%**	**-1.8%**
Total Utilizing Beneficiaries	4,794,124	5,185,858	4,918,317	**-7.6%**	**-2.5%**
Total Paid Rx Claims	26,725,174	28,266,147	27,086,300	**-5.5%**	**-1.3%**
Average Paid Rx Claims per Eligible Beneficiary	1.71	1.79	1.70	**-4.6%**	**0.5%**
Average Paid Rx Claims per Utilizing Beneficiary	5.57	5.45	5.51	**2.3%**	**1.2%**
Fee-for-Service Enrollees					
Total Eligible Beneficiaries	3,195,377	3,340,048	3,453,510	**-4.3%**	**-7.5%**
Total Utilizing Beneficiaries	468,879	514,312	496,042	**-8.8%**	**-5.5%**
Total Paid Rx Claims	1,685,228	1,817,739	1,780,398	**-7.3%**	**-5.4%**
Average Paid Rx Claims per Eligible Beneficiary	0.53	0.54	0.52	**-3.1%**	**2.3%**
Average Paid Rx Claims per Utilizing Beneficiary	3.59	3.53	3.59	**1.7%**	**0.1%**
Managed Care Plan Enrollees					
Total Eligible Beneficiaries	12,893,789	12,918,400	13,026,057	**-0.2%**	**-1.0%**
Total Utilizing Beneficiaries	4,354,430	4,702,304	4,447,120	**-7.4%**	**-2.1%**
Total Paid Rx Claims	25,033,226	26,432,598	25,274,048	**-5.3%**	**-5.5%**
Average Paid Rx Claims per Eligible Beneficiary	1.94	2.05	1.94	**-5.1%**	**0.1%**
Average Paid Rx Claims per Utilizing Beneficiary	5.75	5.62	5.68	**2.3%**	**1.2%**

Table 2. Pharmacy Utilization by Age Group in the Medi-Cal Population.

This table presents pharmacy utilization data in the Medi-Cal program, broken out by age group, including the percent change from the prior quarter and prior-year quarter.

Table 2: Pharmacy Utilization by Age Group for the Entire Medi-Cal Population						
Age Group (years)	**Current Quarter 2018 Q2 Total Paid Claims**	**% Change from *Prior Quarter***	**% Change from *Prior-Year Quarter***	**Current Quarter Total Utilizing Beneficiaries**	**% Change from *Prior Quarter***	**% Change from *Prior-Year Quarter***
0 – 12	2,744,429	**-26.5%**	**-10.8%**	992,196	**-21.3%**	**-10.0%**
13 – 18	1,322,853	**-12.2%**	**0.3%**	411,368	**-11.7%**	**-1.3%**
19 – 39	5,746,489	**-2.6%**	**0.2%**	1,292,450	**-2.8%**	**-0.5%**
40 – 64	14,493,798	**-1.3%**	**-0.9%**	1,652,603	**-1.5%**	**-0.7%**
65+	2,417,597	**-0.7%**	**3.6%**	445,505	**-1.7%**	**2.3%**
Total*	26,725,174	**-5.5%**	**-1.3%**	4,794,124	**-7.6%**	**-2.5%**

* Unknowns represent less than 1% of total

Table 3. Top 20 Drug Therapeutic Categories in the Medi-Cal Population.

This table presents utilization of the top 20 drug therapeutic categories in the Medi-Cal program, by **total utilizing beneficiaries.** The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization and reimbursement dollars paid to pharmacies for these top utilized drugs. The prior-year quarter ranking of the drug therapeutic category is listed for reference.

Table 3: Top 20 Drug Therapeutic Categories by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population

Rank	Last Year Rank	Drug Therapeutic Category Description	Current Quarter 2018 Q2 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries from *Prior Quarter*	% Change Utilizing Total Utilizing Beneficiaries *Prior-Year Quarter*
1	1	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	1,306,284	-15.3%	-2.9%	998,327	20.8%	-2.4%	-0.3%
2	2	PENICILLIN ANTIBIOTICS	614,701	-28.4%	-6.9%	565,834	11.8%	-3.4%	-0.6%
3	3	ANTIHISTAMINES - 2ND GENERATION	798,362	3.3%	-1.6%	511,322	10.7%	0.8%	-0.2%
4	4	ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	952,563	1.7%	2.5%	494,380	10.3%	0.9%	0.6%
5	7	ANTICONVULSANTS	945,097	1.2%	2.4%	420,522	8.8%	0.7%	0.4%
6	6	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	659,655	-22.2%	-5.1%	416,520	8.7%	-2.3%	-0.5%
7	8	PLATELET AGGREGATION INHIBITORS	752,005	1.5%	0.1%	395,439	8.3%	0.7%	0.3%
8	5	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	621,906	-3.5%	-17.2%	385,966	8.1%	0.3%	-1.4%
9	10	TOPICAL ANTI-INFLAMMATORY STEROIDAL	436,397	6.4%	0.2%	348,689	7.3%	1.0%	0.2%
10	9	ANTIHYPERTENSIVES, ACE INHIBITORS	672,658	-0.8%	-5.1%	341,848	7.1%	0.5%	-0.1%
11	16	VITAMIN D PREPARATIONS	600,722	6.7%	14.4%	325,496	6.8%	0.9%	1.0%
12	12	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	683,909	0.8%	-0.2%	325,199	6.8%	0.5%	0.2%
13	11	PROTON-PUMP INHIBITORS	590,550	-0.2%	-3.8%	323,358	6.7%	0.5%	-0.1%
14	13	LAXATIVES AND CATHARTICS	471,988	0.4%	0.4%	314,725	6.6%	0.5%	0.2%
15	14	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	589,990	0.4%	-2.6%	304,173	6.3%	0.5%	0.1%
16	15	NASAL ANTI-INFLAMMATORY STEROIDS	392,512	2.4%	-0.4%	283,246	5.9%	0.4%	-0.0%
17	17	ANTIHISTAMINES – 1ST GENERATION	376,746	-7.3%	-4.9%	256,425	5.4%	-0.2%	-0.3%
18	19	CALCIUM CHANNEL BLOCKING AGENTS	488,658	1.0%	0.7%	246,079	5.1%	0.4%	0.3%
19	18	ANTIEMETIC/ANTIVERTIGO AGENTS	273,969	-11.1%	-11.6%	223,335	4.7%	-0.3%	-0.6%
20	22	BETA-ADRENERGIC BLOCKING AGENTS	446,664	-0.1%	-3.0%	222,433	4.6%	0.3%	0.0%

Table 4. Top 20 Drug Therapeutic Categories in the Medi-Cal Population, by Program.
This table presents utilization of the top 20 drug therapeutic categories in the Medi-Cal program, by **total utilizing beneficiaries stratified by Medi-Cal program.**

Table 4: Top 20 Drug Therapeutic Categories by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Quarter 2018 Q2					
		Total Paid Claims			Total Utilizing Beneficiaries		
Rank	Drug Therapeutic Category Description	Medi-Cal	% FFS	% MCP	Medi-Cal	% FFS	% MCP
1	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	1,206,284	**7.9%**	**92.1%**	998,327	**8.4%**	**91.6%**
2	PENICILLIN ANTIBIOTICS	614,701	**8.0%**	**92.0%**	565,834	**8.1%**	**91.9%**
3	ANTIHISTAMINES - 2ND GENERATION	798,362	**5.7%**	**94.3%**	511,322	**5.9%**	**94.1%**
4	ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	952,563	**4.8%**	**95.2%**	494,380	**6.1%**	**93.9%**
5	ANTICONVULSANTS	945,097	**7.7%**	**92.3%**	420,522	**8.2%**	**91.8%**
6	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	659,655	**5.9%**	**94.1%**	416,520	**6.6%**	**93.4%**
7	PLATELET AGGREGATION INHIBITORS	752,005	**7.4%**	**92.6%**	395,439	**9.6%**	**90.4%**
8	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	621,906	**6.7%**	**93.3%**	385,966	**9.0%**	**91.0%**
9	TOPICAL ANTI-INFLAMMATORY STEROIDAL	436,397	**5.4%**	**94.6%**	348,689	**5.9%**	**94.1%**
10	ANTIHYPERTENSIVES, ACE INHIBITORS	672,658	**5.7%**	**94.3%**	341,848	**8.2%**	**91.8%**
11	VITAMIN D PREPARATIONS	600,722	**0.6%**	**99.4%**	325,496	**0.7%**	**99.3%**
12	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	683,909	**5.5%**	**94.5%**	325,199	**6.5%**	**93.5%**
13	PROTON-PUMP INHIBITORS	590,550	**3.4%**	**96.6%**	323,358	**3.8%**	**96.2%**
14	LAXATIVES AND CATHARTICS	471,988	**9.2%**	**90.8%**	314,725	**9.2%**	**90.8%**
15	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	589,990	**6.7%**	**93.3%**	304,173	**8.7%**	**91.3%**
16	NASAL ANTI-INFLAMMATORY STEROIDS	392,512	**2.1%**	**97.9%**	283,246	**2.4%**	**97.6%**
17	ANTIHISTAMINES – 1ST GENERATION	376,746	**7.2%**	**92.8%**	256,425	**7.6%**	**92.4%**
18	CALCIUM CHANNEL BLOCKING AGENTS	488,658	**5.4%**	**94.6%**	246,079	**6.8%**	**93.2%**
19	ANTIEMETIC/ANTIVERTIGO AGENTS	273,969	**7.9%**	**92.1%**	223,335	**8.2%**	**91.8%**
20	BETA-ADRENERGIC BLOKING AGENTS	446,664	**5.2%**	**94.8%**	222,433	**6.4%**	**93.6%**

Table 5. Top 20 Drugs in the Medi-Cal Population.

This table presents utilization of the top 20 drugs in the Medi-Cal program, by **total utilizing beneficiaries.** The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization for these drugs. The prior-year quarter ranking of each drug is listed for reference.

Table 5: Top 20 Drugs by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population

Rank	Last Year Rank	Drug Description	Current Quarter 2018 Q2 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries from *Prior Quarter*	% Change Utilizing Total Utilizing Beneficiaries *Prior-Year Quarter*
1	1	IBUPROFEN	937,389	-19.9%	-3.4%	750,816	15.7%	-2.7%	-0.3%
2	2	ALBUTEROL SULFATE	663,940	-23.3%	-5.5%	422,423	8.8%	-2.5%	-0.6%
3	3	AMOXICILLIN	454,515	-30.0%	-7.6%	416,754	8.7%	-2.8%	-0.5%
4	5	ASPIRIN	698,931	1.4%	-0.3%	371,363	7.7%	0.7%	0.3%
5	4	LORATADINE	566,417	0.7%	-5.5%	360,630	7.5%	0.4%	-0.5%
6	7	FLUTICASONE PROPIONATE	452,275	4.6%	7.2%	320,747	6.7%	0.5%	0.4%
7	9	ATORVASTATIN CALCIUM	591,335	4.2%	14.8%	310,888	6.5%	0.7%	1.0%
8	8	METFORMIN HCL	589,990	0.4%	-2.6%	304,173	6.3%	0.5%	0.1%
9	6	HYDROCODONE/ ACETAMINOPHEN	457,010	-3.3%	-17.9%	272,651	5.7%	0.2%	-1.0%
10	10	LISINOPRIL	509,654	0.1%	-2.3%	257,790	5.4%	0.4%	0.1%
11	11	OMEPRAZOLE	402,817	-0.4%	-4.7%	221,414	4.6%	0.3%	-0.1%
12	12	ACETAMINOPHEN	253,149	-29.8%	-4.0%	215,851	4.5%	-1.5%	-0.1%
13	14	BLOOD SUGAR DIAGNOSTIC	378,934	1.8%	3.3%	213,557	4.5%	0.4%	0.2%
14	16	AMLODIPINE BESYLATE	419,083	1.3%	1.6%	211,506	4.4%	0.4%	0.3%
15	17	GABAPENTIN	435,864	1.7%	4.1%	210,109	4.4%	0.4%	0.3%
16	15	CEPHALEXIN	216,142	0.0%	-3.5%	201,522	4.2%	0.3%	-0.0%
17	20	CHOLECALCIFEROL (VITAMIN D)	345,388	7.7%	21.1%	192,926	4.0%	0.6%	0.7%
18	13	AZITHROMYCIN	195,114	-45.3%	-18.0%	182,657	3.8%	-2.6%	-0.7%
19	18	FERROUS SULFATE	275,736	1.9%	2.0%	175,073	3.7%	0.3%	0.1%
20	19	LEVOTHYROXINE SODIUM	362,642	0.7%	-0.8%	171,551	3.6%	0.3%	0.1%

Table 6. Top 20 Drugs in the Medi-Cal Population, by Program.

This table presents utilization of the top 20 drug therapeutic categories in the Medi-Cal program, by **total utilizing beneficiaries stratified by Medi-Cal program.**

Table 6: Top 20 Drugs by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population, by Program

		Current Quarter 2018 Q2					
		Total Paid Claims			Total Utilizing Beneficiaries		
Rank	Drug Description	Medi-Cal	% FFS	% MCP	Medi-Cal	% FFS	% MCP
1	IBUPROFEN	937,389	**8.3%**	**91.7%**	750,816	**9.2%**	**90.8%**
2	ALBUTEROL SULFATE	663,940	**5.9%**	**94.1%**	422,423	**6.6%**	**93.4%**
3	AMOXICILLIN	454,515	**7.6%**	**92.4%**	416,754	**7.6%**	**92.4%**
4	ASPIRIN	698,931	**7.6%**	**92.4%**	371,363	**9.9%**	**90.1%**
5	LORATADINE	566,417	**7.8%**	**92.2%**	360,630	**8.2%**	**91.8%**
6	FLUTICASONE PROPIONATE	452,275	**2.6%**	**97.4%**	320,747	**3.0%**	**97.0%**
7	ATORVASTATIN CALCIUM	591,335	**5.1%**	**94.9%**	310,888	**6.4%**	**93.6%**
8	METFORMIN HCL	589,990	**6.7%**	**93.3%**	304,173	**8.7%**	**91.3%**
9	HYDROCODONE/ACETAMINOPHEN	457,010	**6.5%**	**93.5%**	272,651	**9.2%**	**90.8%**
10	LISINOPRIL	509,654	**6.4%**	**93.6%**	257,790	**8.4%**	**91.6%**
11	OMEPRAZOLE	402,817	**0.3%**	**99.7%**	221,414	**0.3%**	**99.7%**
12	ACETAMINOPHEN	253,149	**5.9%**	**94.1%**	215,851	**6.5%**	**93.5%**
13	BLOOD SUGAR DIAGNOSTIC	378,934	**0.1%**	**99.9%**	213,557	**0.2%**	**99.8%**
14	AMLODIPINE BESYLATE	419,083	**5.2%**	**94.8%**	211,506	**6.6%**	**93.4%**
15	GABAPENTIN	435,864	**5.4%**	**94.6%**	210,109	**6.4%**	**93.6%**
16	CEPHALEXIN	216,142	**11.0%**	**89.0%**	201,522	**11.1%**	**88.9%**
17	CHOLECALCIFEROL (VITAMIN D)	345,388	**0.6%**	**99.4%**	192,926	**0.6%**	**99.4%**
18	AZITHROMYCIN	195,114	**7.5%**	**92.5%**	182,657	**7.4%**	**92.6%**
19	FERROUS SULFATE	275,736	**14.0%**	**86.0%**	175,073	**16.6%**	**83.4%**
20	LEVOTHYROXINE SODIUM	362,642	**6.1%**	**93.9%**	171,551	**7.4%**	**92.6%**

QUARTERLY SUMMARY
MEDI-CAL FEE-FOR-SERVICE PROGRAM DRUG USE REVIEW
REPORT PERIOD: 4th QUARTER 2018 (OCTOBER – DECEMBER 2018)

Executive Summary

The DUR quarterly report provides information on both prospective and retrospective drug utilization for all claims processed by the Medi-Cal Fee-for-Service (FFS) program, including the carved-out drug claims for the Medi-Cal Managed Care Plans (MCPs). For this quarterly report, the prospective and retrospective data cover the fourth quarter of 2018 (2018 Q4). All tables can be found in **Appendix A** and definitions of selected terms can be found in **Appendix B**.

Prospective DUR

As shown in Table 1.1, in comparison to the prior quarter (2018 Q3), in 2018 Q4 overall drug claims and total DUR alerts increased by 1%. In comparison to the prior-year quarter (2017 Q4), overall drug claims decreased by 1% while total DUR alerts increased by 2%.

A comparison between 2018 Q4 and 2018 Q3 showed very little change among the summary of alert transactions by therapeutic problem (**Table 1.2**) and among the top 10 drugs for each of the 12 prospective DUR alerts (**Tables 2.1-2.12**).

Retrospective DUR

Due to a slight lag in processing time, the aggregate tables contain complete retrospective claims data, while the stratified tables are not yet complete for 2018 Q4. For this report, the stratified tables represent 95.1% of total paid claims represented in the aggregated tables.

In 2018 Q4, approximately 14% of eligible Medi-Cal FFS enrollees had a paid claim through the Medi-Cal fee-for-service program, compared with only 2% of Medi-Cal MCP enrollees (**Table 3.2** and **Table 3.3**). Among all Medi-Cal beneficiaries with a paid claim through the Medi-Cal fee-for-service program in 2018 Q4, 57% were FFS enrollees and 35% were MCP enrollees (numbers add up to less than 100% due to the lag in processing time).

As shown in **Table 4.1**, total utilizing beneficiaries and total paid claims decreased across all age groups in comparison to the prior-year quarter. The greatest decrease in utilizing beneficiaries and paid claims processed by the FFS program in comparison to the prior-year quarter was in the FFS population (**Table 4.2**). A review of fee-for-service paid claims for the Medi-Cal MCP population (**Table 4.3**) shows that in comparison to the prior-year quarter, there was an increase in total utilizing beneficiaries and total paid claims in all three of the adult age groups.

Of note, **Table 5.2** and **Table 6.2** show the top 20 drug therapeutic drug categories and top 20 drugs of Medi-Cal FFS program enrollees, while **Table 5.3** and **Table 6.3** show the top 20 drug therapeutic drug categories and top 20 drugs by beneficiaries enrolled in Medi-Cal MCPs. These tables give a more in-depth look at the impact of carved-out drugs on tables showing overall pharmacy utilization in the Medi-Cal fee-for-service program **(Table 5.1** and **Table 6.1**). **Table 6.3** shows significant across-the-board increases in the use of NALOXONE and BUPRENORPHINE HCL/NALOXONE HCL in the MCP population during 2018 Q4.

Appendix A: Prospective and Retrospective DUR Tables

Tables 1.1-1.2. Summary of Prospective DUR Alert Transactions in the Medi-Cal Fee-for-Service Program..

Table 1.1 provides summary level data (by volume) on pharmacy claims and DUR alert activities, including data and percent change from the prior quarter. Alerts are generated after adjudication of drug claims which exceed or otherwise fall outside of certain prescribed parameters. Please see **Appendix B** for definitions of terms used in this DUR report.

Table 1.1: Summary of Alert Transactions					
Category	Current Quarter 2018 Q4 (Jul – Sept 2018)	Prior Quarter 2018 Q3 (Apr – Jun 2018)	% Change from *Prior Quarter*	Prior-Year Quarter 2017 Q4 (Jul – Sept 2017)	% Change from *Prior-Year Quarter*
Drug Claims	7,760,490	7,656,519	**1.4%**	7,828,783	**-0.9%**
DUR Drug Claims	3,714,099	3,712,001	**0.1%**	3,807,861	**-2.5%**
Total Alerts	1,049,489	1,044,395	**0.5%**	1,032,634	**1.6%**
Total Alert Overrides	675,741	666,064	**1.5%**	640,248	**5.5%**
Total Alert Cancels	254	386	**-34.2%**	230	**10.4%**

Note: Drug claims receiving multiple alerts can be adjudicated by pharmacists by responding to only one conflict code, followed by an intervention code and outcome code. The remaining alerts on the claim cannot be tracked as they are overridden by the pharmacist's response to a single alert. For example, a single claim can generate up to eight different alerts, but the pharmacist can override all eight alerts by choosing to override only one alert. In addition, the number of cancelled alerts may be underrepresented due to the system's inability to capture claims that were not adjudicated.

Table 1.2 provides a summary of the number of drug claims and alerts generated for each therapeutic problem type (sorted by alert frequency). Total alerts not adjudicated may be overrepresented, as claims with multiple alerts that have been adjudicated under one alert will show up as not adjudicated for the remaining alerts.

Table 1.2: Summary of Alert Transactions by Therapeutic Problem Type – 2018 Q4							
Therapeutic Problem Type	Total Alerts	Total Alert Over-rides	% Alert Over-rides	Total Alert Cancels	% Alert Cancels	Total Alerts Not Adjud-icated	% Alerts Not Adjud-icated
Therapeutic Duplication (TD)	366,911	279,216	76.1%	50	0.0%	87,645	23.9%
Early Refill (ER)	273,689	93,765	34.3%	108	0.0%	179,816	65.7%
Ingredient Duplication (ID)	181,826	133,520	73.4%	30	0.0%	48,276	26.6%
Late Refill (LR)	107,625	83,986	78.0%	41	0.0%	23,598	21.9%
Total High Dose (HD)	44,423	29,046	65.4%	6	0.0%	15,371	34.6%
Additive Toxicity (AT)	33,516	27,453	81.9%	2	0.0%	6,061	18.1%
Drug-Pregnancy (PG)	20,734	13,939	67.2%	14	0.1%	6,781	32.7%
Total Low Dose (LD)	11,654	7,970	68.4%	1	0.0%	3,683	31.6%
Drug-Drug (DD)	6,276	4,866	77.5%	0	0.0%	1,410	22.5%
Drug-Disease (MC)	2,331	1,666	71.5%	0	0.0%	665	28.5%
Drug-Age (PA)	335	206	61.5%	0	0.0%	129	38.5%
Drug-Allergy (DA)	169	108	63.9%	0	0.0%	61	36.1%

Tables 2.1-2.12. Prospective DUR Alert Transactions by Therapeutic Problem Type in the Medi-Cal Fee-for-Service Program.

Each of the following tables provides greater detail of each of the 12 DUR alerts with the top 10 drugs generating each respective alert. For each of the top 10 drugs, data are provided for the total number of adjudicated alerts, alert overrides, alert cancels, paid claims, and the percentage of paid claims with alert overrides. **Tables are listed in order of DUR alert priority, which is determined by the DUR Board.**

Table 2.1: Top 10 Drugs by Therapeutic Problem Type – Drug-Allergy (DA) – 2018 Q4

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	PHENYTOIN SODIUM EXTENDED	74	74	0	1,718	4.3%
2	PHENYTOIN	49	49	0	720	6.8%
3	OXYCODONE HCL	13	13	0	3,888	0.3%
4	OXYCODONE HCL/ACETAMINOPHEN	5	5	0	4,151	0.1%
5	AMOXICILLIN	4	4	0	32,812	0.0%
6	AMOXICILLIN/POTASSIUM CLAV	4	4	0	10,059	0.0%
7	ARIPIPRAZOLE	3	3	0	103,831	0.0%
8	ASPIRIN	3	3	0	48,534	0.0%
9	HALOPERIDOL	2	2	0	19,520	0.0%
10	IBUPROFEN	2	2	0	77,903	0.0%

Table 2.2: Top 10 Drugs by Therapeutic Problem Type – Drug-Pregnancy (PG) – 2018 Q4

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	IBUPROFEN	12,762	12,750	12	77,903	16.4%
2	NORETHINDRONE	2,234	2,233	1	6,886	32.4%
3	MISOPROSTOL	359	359	0	486	73.9%
4	METHYLERGONOVINE MALEATE	229	229	0	141	162.4%
5	NAPROXEN	220	220	0	11,709	1.9%
6	LISINOPRIL	135	135	0	31,081	0.4%
7	METHIMAZOLE	122	121	1	1,453	8.3%
8	FERROUS SULFATE	116	116	0	36,028	0.3%
9	DOCUSATE SODIUM	114	114	0	37,934	0.3%
10	ULIPRISTAL ACETATE	100	100	0	741	13.5%

Table 2.3: Top 10 Drugs by Therapeutic Problem Type – Drug-Disease (MC) – 2018 Q4

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	METFORMIN HCL	415	414	1	39,647	1.0%
2	POTASSIUM CHLORIDE	330	330	0	3,100	10.6%
3	HALOPERIDOL	306	306	0	19,520	1.6%
4	CARBAMAZEPINE	57	57	0	2,843	2.0%
5	METOPROLOL SUCCINATE	57	57	0	5,846	1.0%
6	METOPROLOL TARTRATE	52	52	0	6,934	0.7%
7	LEVONORGESTREL-ETHIN ESTRADIOL	46	46	0	16,416	0.3%
8	NORELGESTROMIN/ETHIN.ESTRADIOL	45	45	0	7,837	0.6%
9	NORGESTIMATE-ETHINYL ESTRADIOL	37	37	0	14,822	0.2%
10	HALOPERIDOL DECANOATE	36	36	0	4,265	0.8%

Table 2.4: Top 10 Drugs by Therapeutic Problem Type – Drug-Drug Interaction (DD) – 2018 Q4						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	ELVITEG/COB/EMTRI/TENOF ALAFEN	652	652	0	12,462	5.2%
2	DARUNAVIR ETHANOLATE	596	596	0	3,489	17.1%
3	GEMFIBROZIL	524	524	0	2,081	25.2%
4	ATORVASTATIN CALCIUM	307	307	0	29,985	1.0%
5	SIMVASTATIN	245	245	0	9,015	2.7%
6	DARUNAVIR/COBICISTAT	171	171	0	5,068	3.4%
7	AMLODIPINE BESYLATE	154	154	0	21,007	0.7%
8	ETRAVIRINE	114	114	0	739	15.4%
9	LURASIDONE HCL	114	114	0	40,572	0.3%
10	BUPRENORPHINE HCL/ NALOXONE HCL	110	110	0	38,470	0.3%

Table 2.5: Top 10 Drugs by Therapeutic Problem Type – Therapeutic Duplication (TD) – 2018 Q4						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	63,491	63,481	10	139,064	45.6%
2	OLANZAPINE	26,039	26,038	1	79,685	32.7%
3	ARIPIPRAZOLE	23,043	23,041	2	103,831	22.2%
4	RISPERIDONE	20,376	20,372	4	81,791	24.9%
5	HALOPERIDOL	14,933	14,931	2	19,520	76.5%
6	LURASIDONE HCL	12,186	12,184	2	40,572	30.0%
7	CLOZAPINE	11,387	11,386	1	21,304	53.4%
8	PALIPERIDONE PALMITATE	7,468	7,468	0	19,522	38.3%
9	CHLORPROMAZINE HCL	5,273	5,272	1	6,026	87.5%
10	ZIPRASIDONE HCL	5,002	5,002	0	16,384	30.5%

Table 2.6: Top 10 Drugs by Therapeutic Problem Type – Overutilization (ER) – 2018 Q4						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	7,548	7,541	7	139,064	5.4%
2	ARIPIPRAZOLE	5,891	5,885	6	103,831	5.7%
3	RISPERIDONE	4,697	4,694	3	81,791	5.7%
4	OLANZAPINE	4,158	4,158	0	79,685	5.2%
5	BENZTROPINE MESYLATE	3,752	3,751	1	54,655	6.9%
6	LITHIUM CARBONATE	2,600	2,598	2	29,403	8.8%
7	LURASIDONE HCL	2,145	2,139	6	40,572	5.3%
8	METFORMIN HCL	1,812	1,811	1	39,647	4.6%
9	ASPIRIN	1,794	1,793	1	48,534	3.7%
10	BUPRENORPHINE HCL/ NALOXONE HCL	1,716	1,715	1	38,470	4.5%

Table 2.7: Top 10 Drugs by Therapeutic Problem Type – Underutilization (LR) – 2018 Q4						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	ARIPIPRAZOLE	14,083	14,082	1	103,831	13.6%
2	QUETIAPINE FUMARATE	12,547	12,539	8	139,064	9.0%
3	RISPERIDONE	8,265	8,263	2	81,791	10.1%
4	OLANZAPINE	7,069	7,067	2	79,685	8.9%
5	BENZTROPINE MESYLATE	6,251	6,248	3	54,655	11.4%
6	LURASIDONE HCL	4,604	4,603	1	40,572	11.3%
7	LITHIUM CARBONATE	3,784	3,784	0	29,403	12.9%
8	ATORVASTATIN CALCIUM	2,982	2,981	1	29,985	9.9%
9	LEVOTHYROXINE SODIUM	2,671	2,670	1	24,137	11.1%
10	GABAPENTIN	2,532	2,528	4	22,826	11.1%

Table 2.8: Top 10 Drugs by Therapeutic Problem Type – Additive Toxicity (AT) – 2018 Q4						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	LITHIUM CARBONATE	1,351	1,351	0	29,403	4.6%
2	LORAZEPAM	1,296	1,296	0	7,515	17.2%
3	CLONAZEPAM	1,129	1,129	0	6,292	17.9%
4	BACLOFEN	1,023	1,023	0	13,163	7.8%
5	HYDROCODONE/ACETAMINOPHEN	876	876	0	25,968	3.4%
6	QUETIAPINE FUMARATE	768	768	0	139,064	0.6%
7	BUSPIRONE HCL	665	665	0	3,326	20.0%
8	ARIPIPRAZOLE	584	584	0	103,831	0.6%
9	TRAZODONE HCL	489	489	0	10,371	4.7%
10	OLANZAPINE	487	487	0	79,685	0.6%

Table 2.9: Top 10 Drugs by Therapeutic Problem Type – Ingredient Duplication (ID) – 2018 Q4						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	OLANZAPINE	14,105	14,102	3	79,685	17.7%
2	ARIPIPRAZOLE	11,812	11,807	5	103,831	11.4%
3	RISPERIDONE	10,713	10,711	2	81,791	13.1%
4	ALBUTEROL SULFATE	7,568	7,566	2	42,424	17.8%
5	QUETIAPINE FUMARATE	6,464	6,464	0	139,064	4.6%
6	CLOZAPINE	5,956	5,956	0	21,304	28.0%
7	LURASIDONE HCL	5,894	5,894	0	40,572	14.5%
8	LEVOTHYROXINE SODIUM	3,136	3,136	0	24,137	13.0%
9	ZIPRASIDONE HCL	2,998	2,998	0	16,384	18.3%
10	HALOPERIDOL	2,572	2,572	0	19,520	13.2%

Table 2.10: Top 10 Drugs by Therapeutic Problem Type – Drug-Age (PA) – 2018 Q4						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	AMITRIPTYLINE HCL	179	179	0	3,092	5.8%
2	ACETAMINOPHEN WITH CODEINE	45	45	0	5,848	0.8%
3	BUDESONIDE	8	8	0	4,007	0.2%
4	CODEINE PHOSPHATE/GUAIFENESIN	8	8	0	3,109	0.3%
5	ARIPIPRAZOLE	6	6	0	103,831	0.0%
6	FERROUS SULFATE	5	5	0	36,028	0.0%
7	DOXEPIN HCL	4	4	0	447	0.9%
8	ACETAMINOPHEN	3	3	0	16,035	0.0%
9	ASPIRIN	3	3	0	48,534	0.0%
10	PROMETHAZINE/ DEXTROMETHORPHAN	3	3	0	14,719	0.0%

Table 2.11: Top 10 Drugs by Therapeutic Problem Type – High Dose (HD) – 2018 Q4						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	OLANZAPINE	6,603	6,601	2	79,685	8.3%
2	RISPERIDONE	2,252	2,252	0	81,791	2.8%
3	IBUPROFEN	1,836	1,836	0	77,903	2.4%
4	QUETIAPINE FUMARATE	1,467	1,467	0	139,064	1.1%
5	GABAPENTIN	1,374	1,374	0	22,826	6.0%
6	HYDROCODONE/ACETAMINOPHEN	941	941	0	25,968	3.6%
7	AMOXICILLIN	825	825	0	32,812	2.5%
8	AMOXICILLIN/POTASSIUM CLAV	720	720	0	10,059	7.2%
9	ARIPIPRAZOLE	533	533	0	103,831	0.5%
10	FAMOTIDINE	429	429	0	13,138	3.3%

Table 2.12: Top 10 Drugs by Therapeutic Problem Type – Low Dose (LD) – 2018 Q4						
Rank	Rank	Rank	Rank	Rank	Rank	Rank
1	AZITHROMYCIN	982	982	0	19,655	5.0%
2	DIVALPROEX SODIUM	669	668	1	10,733	6.2%
3	ERYTHROMYCIN ETHYLSUCCINATE	439	439	0	1,694	25.9%
4	DULOXETINE HCL	415	415	0	4,004	10.4%
5	LITHIUM CARBONATE	393	393	0	29,403	1.3%
6	AMOXICILLIN/POTASSIUM CLAV	324	324	0	10,059	3.2%
7	BUPROPION HCL	319	319	0	5,841	5.5%
8	ALBUTEROL SULFATE	293	293	0	42,424	0.7%
9	AMOXICILLIN	238	238	0	32,812	0.7%
10	SULFAMETHOXAZOLE/TRIMETHOPRIM	187	187	0	15,460	1.2%

Tables 3.1-3.3. Summary of Medi-Cal Fee-for-Service Pharmacy Utilization.
These tables shows pharmacy utilization in the Medi-Cal Fee-for-Service program, including the percent change from the prior quarter and prior-year quarter. Beneficiaries with enrollments in both FFS and MCP during the quarter may be counted in both **Table 3.2** and **Table 3.3**, as enrollment status may change.

Table 3.1: Fee-for-Service Pharmacy Utilization Measures for the Entire Medi-Cal Population

Category	Current Quarter 2018 Q4	Prior Quarter 2018 Q3	Prior-Year Quarter 2017 Q4	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*
Total Eligible Beneficiaries	15,520,151	15,768,314	15,969,745	-1.6%	-2.8%
Total Utilizing Beneficiaries	787,056	790,535	830,975	-0.4%	-5.3%
Total Paid Rx Claims	2,620,546	2,621,898	2,744,886	-0.1%	-4.5%
Average Paid Rx Claims per Eligible Beneficiary	0.17	0.17	0.17	1.5%	-1.8%
Average Paid Rx Claims per Utilizing Beneficiary	3.33	3.32	3.30	0.4%	0.8%

Table 3.2: Fee-for-Service Pharmacy Utilization Measures for the Medi-Cal FFS Population Only

Category	Current Quarter 2018 Q4	Prior Quarter 2018 Q3	Prior-Year Quarter 2017 Q4	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*
Total Eligible Beneficiaries	3,120,220	3,203,969	3,323,170	-2.6%	-6.1%
Total Utilizing Beneficiaries	445,230	444,612	477,096	0.1%	-6.7%
Total Paid Rx Claims	1,576,777	1,583,159	1,680,361	-0.4%	-6.2%
Average Paid Rx Claims per Eligible Beneficiary	0.51	0.49	0.51	2.3%	-0.1%
Average Paid Rx Claims per Utilizing Beneficiary	3.54	3.56	3.52	-0.6%	0.5%

Table 3.3: Fee-for-Service Pharmacy Utilization Measures for the Medi-Cal MCP Population Only

Category	Current Quarter 2018 Q4	Prior Quarter 2018 Q3	Prior-Year Quarter 2017 Q4	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*
Total Eligible Beneficiaries	12,799,696	12,977,649	13,077,047	-1.4%	-2.1%
Total Utilizing Beneficiaries	274,680	275,395	268,540	-0.3%	2.3%
Total Paid Rx Claims	914,534	915,414	897,502	-0.1%	1.9%
Average Paid Rx Claims per Eligible Beneficiary	0.07	0.07	0.07	1.3%	4.1%
Average Paid Rx Claims per Utilizing Beneficiary	3.33	3.32	3.34	0.2%	-0.4%

Tables 4.1-4.3. Fee-for-Service Pharmacy Utilization by Age Group in the Medi-Cal Population.

These tables present pharmacy utilization data in the Medi-Cal Fee-for-Service program, broken out by age group, including the percent change from the prior quarter and prior-year quarter. Beneficiaries with enrollments in both FFS and MCP during the quarter may be counted in both **Table 4.2** and **Table 4.3**, as enrollment status may change.

Table 4.1: Fee-for-Service Pharmacy Utilization by Age Group for the Entire Medi-Cal Population

Age Group (years)	Current Quarter 2018 Q4 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*
0 – 12	274,659	**6.1%**	**-13.1%**	87,169	**5.7%**	**-15.0%**
13 – 18	173,275	**-0.6%**	**-4.8%**	44,607	**-1.2%**	**-4.3%**
19 – 39	798,142	**-0.8%**	**-1.3%**	258,076	**-1.7%**	**-2.6%**
40 – 64	1,094,770	**0.0%**	**-2.2%**	279,557	**0.1%**	**-0.7%**
65+	196,156	**-1.1%**	**-8.3%**	64,930	**-0.9%**	**-9.4%**
Total*	2,620,546	**-0.1%**	**-4.5%**	787,056	**-0.4%**	**-5.3%**

Table 4.2: Fee-for-Service Pharmacy Utilization by Age Group for the Medi-Cal FFS Population Only

Age Group (years)	Current Quarter 2018 Q4 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*
0 – 12	170,329	**11.0%**	**-15.7%**	65,386	**8.8%**	**-16.5%**
13 – 18	90,351	**-0.4%**	**-6.8%**	24,018	**-1.0%**	**-6.2%**
19 – 39	452,647	**-2.3%**	**-4.9%**	147,596	**-2.5%**	**-5.0%**
40 – 64	676,762	**-1.1%**	**-3.4%**	146,538	**0.1%**	**-1.8%**
65+	186,687	**-2.6%**	**-8.9%**	61,691	**-1.4%**	**-10.1%**
Total*	1,576,777	**-0.4%**	**-6.2%**	445,230	**0.1%**	**-6.7%**

Table 4.3: Fee-for-Service Pharmacy Utilization by Age Group for the Medi-Cal MCP Population Only

Age Group (years)	Current Quarter 2018 Q4 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*
0 – 12	91,067	**-2.4%**	**-4.5%**	19,835	**-2.9%**	**-6.1%**
13 – 18	78,276	**-2.6%**	**-1.5%**	20,220	**-3.0%**	**-1.2%**
19 – 39	327,889	**1.1%**	**6.6%**	102,404	**0.2%**	**6.0%**
40 – 64	408,027	**-0.1%**	**0.4%**	128,851	**0.1%**	**1.3%**
65+	9,275	**1.8%**	**6.5%**	3,370	**4.5%**	**7.7%**
Total*	914,534	**-0.1%**	**1.9%**	274,680	**-0.3%**	**2.3%**

* Unknowns represent less than 1% of total

Tables 5.1-5.3. Top 20 Fee-for-Service Drug Therapeutic Categories in the Medi-Cal Population.

These tables present utilization of the top 20 drug therapeutic categories in the Medi-Cal Fee-for-Service program, by **total utilizing beneficiaries.** The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization and reimbursement dollars paid to pharmacies for these top utilized drugs. The prior-year quarter ranking of the drug therapeutic category is listed for reference.

Table 5.1: Top 20 Fee-for-Service Drug Therapeutic Categories by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population

Rank	Last Year Rank	Drug Therapeutic Category Description	Current Quarter 2018 Q4 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries from *Prior Quarter*	% Change Utilizing Total Utilizing Beneficiaries *Prior-Year Quarter*
1	1	ANTIPSYCHOTIC,ATYPICAL,DOPAMINE ,SEROTONIN ANTAGNST	409,347	**1.0%**	**2.5%**	137,564	17.5%	**-0.4%**	**0.5%**
2	2	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	95,200	**2.0%**	**-7.1%**	81,427	10.3%	**1.9%**	**-7.4%**
3	3	CONTRACEPTIVES,ORAL	73,079	**-6.7%**	**-14.4%**	55,512	7.1%	**-6.1%**	**-13.9%**
4	5	ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	109,925	**0.9%**	**4.6%**	46,991	6.0%	**-0.5%**	**2.8%**
5	4	PENICILLIN ANTIBIOTICS	47,008	**9.5%**	**-12.6%**	42,418	5.4%	**9.8%**	**-12.5%**
6	6	PLATELET AGGREGATION INHIBITORS	50,828	**-3.8%**	**-15.1%**	34,029	4.3%	**-4.3%**	**-15.1%**
7	9	ANTICONVULSANTS	84,248	**-1.6%**	**-2.1%**	31,292	4.0%	**-2.9%**	**-2.5%**
8	8	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	43,367	**19.9%**	**-10.6%**	29,378	3.7%	**23.0%**	**-13.8%**
9	7	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	35,941	**-12.0%**	**-23.0%**	28,872	3.7%	**-12.4%**	**-23.0%**
10	14	ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	43,753	**-0.3%**	**2.4%**	28,823	3.7%	**0.1%**	**3.2%**
11	10	LAXATIVES AND CATHARTICS	43,324	**-4.2%**	**-10.1%**	28,291	3.6%	**-4.0%**	**-10.4%**
12	13	ANTIHYPERTENSIVES, ACE INHIBITORS	42,480	**-1.3%**	**-3.7%**	27,762	3.5%	**-1.0%**	**-2.8%**
13	11	IRON REPLACEMENT	36,218	**-8.6%**	**-9.9%**	26,927	3.4%	**-9.1%**	**-10.3%**
14	15	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	39,671	**-1.8%**	**0.1%**	26,357	3.3%	**-1.5%**	**1.0%**
15	12	ANTIHISTAMINES - 2ND GENERATION	38,580	**1.4%**	**-11.1%**	25,326	3.2%	**3.5%**	**-11.5%**
16	16	ANTIPARKINSONISM DRUGS,ANTICHOLINERGIC	59,148	**-1.5%**	**-2.1%**	23,027	2.9%	**-2.0%**	**-3.7%**
17	17	CEPHALOSPORIN ANTIBIOTICS - 1ST GENERATION	23,563	**-8.9%**	**-6.0%**	22,145	2.8%	**-8.8%**	**-5.7%**
18	21	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	36,439	**0.5%**	**-0.2%**	20,132	2.6%	**0.2%**	**-1.0%**
19	26	ANTIEMETIC/ANTIVERTIGO AGENTS	25,245	**11.6%**	**6.9%**	19,980	2.5%	**13.5%**	**7.9%**
20	18	MACROLIDE ANTIBIOTICS	22,607	**27.0%**	**-11.8%**	19,671	2.5%	**30.0%**	**-13.1%**

Table 5.2: Top 20 Fee-for-Service Drug Therapeutic Categories by *Total Utilizing Beneficiaries* for the Medi-Cal FFS Population Only

Rank	Last Year Rank	Drug Therapeutic Category Description	Current Quarter 2018 Q4 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries from *Prior Quarter*	% Change Utilizing Total Utilizing Beneficiaries *Prior-Year Quarter*
1	1	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	93,662	**2.0%**	**-6.7%**	81,968	18.41%	**1.8%**	**-7.1%**
2	2	PENICILLIN ANTIBIOTICS	45,895	**9.7%**	**-12.1%**	42,575	9.56%	**9.9%**	**-12.0%**
3	3	PLATELET AGGREGATION INHIBITORS	49,818	**-3.8%**	**-15.0%**	34,034	7.64%	**-4.1%**	**-14.9%**
4	5	ANTICONVULSANTS	67,920	**-3.2%**	**-2.3%**	32,306	7.26%	**-3.4%**	**-2.3%**
5	4	OPIOID ANALGESIC AND NON-SALICYLATE ANALGESICS	35,341	**-12.2%**	**-22.5%**	29,209	6.56%	**-12.5%**	**-22.8%**
6	10	ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	43,196	**-1.4%**	**2.8%**	28,642	6.43%	**-0.2%**	**3.5%**
7	6	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	39,344	**21.2%**	**-11.5%**	27,661	6.21%	**24.1%**	**-13.9%**
8	7	LAXATIVES AND CATHARTICS	40,888	**-4.4%**	**-9.9%**	27,346	6.14%	**-4.1%**	**-9.7%**
9	11	ANTIHYPERTENSIVES, ACE INHIBITORS	39,069	**-1.6%**	**-3.2%**	26,067	5.85%	**-0.8%**	**-2.1%**
10	9	IRON REPLACEMENT	34,777	**-8.4%**	**-7.3%**	26,028	5.85%	**-8.7%**	**-6.7%**
11	12	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	37,428	**-2.3%**	**0.8%**	25,193	5.66%	**-1.5%**	**1.7%**
12	8	ANTIHISTAMINES - 2ND GENERATION	37,447	**1.2%**	**-11.4%**	24,794	5.57%	**3.5%**	**-11.4%**
13	13	CEPHALOSPORIN ANTIBIOTICS - 1ST GENERATION	22,373	**-9.2%**	**-4.8%**	21,045	4.73%	**-9.0%**	**-4.4%**
14	19	ANTIEMETIC/ANTIVERTIGO AGENTS	23,992	**11.9%**	**8.8%**	20,681	4.65%	**15.1%**	**11.8%**
15	14	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	35,893	**-0.4%**	**0.0%**	20,141	4.52%	**-0.1%**	**-0.7%**
16	15	ANTIHISTAMINES - 1ST GENERATION	24,950	**-2.6%**	**-8.5%**	18,081	4.06%	**-3.1%**	**-8.6%**
17	16	PRENATAL VITAMIN PREPARATIONS	20,131	**-6.5%**	**-10.0%**	17,978	4.04%	**-8.8%**	**-9.1%**
18	17	TOPICAL ANTI-INFLAMMATORY STEROIDAL	20,450	**-9.6%**	**-9.2%**	17,716	3.98%	**-9.7%**	**-9.8%**
19	20	INSULINS	29,966	**-3.5%**	**-2.4%**	17,135	3.85%	**-2.8%**	**-2.6%**
20	18	GLUCOCORTICOIDS	20,682	**20.9%**	**-11.0%**	16,816	3.78%	**22.8%**	**-12.1%**

Table 5.3: Top 20 Fee-for-Service Drug Therapeutic Categories by *Total Utilizing Beneficiaries* for the Medi-Cal MCP Population Only

Rank	Last Year Rank	Drug Therapeutic Category Description	Current Quarter 2018 Q4 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries from *Prior Quarter*	% Change Utilizing Total Utilizing Beneficiaries *Prior-Year Quarter*
1	1	ANTIPSYCHOTIC,ATYPICAL,DOPAMINE ,SEROTONIN ANTAGNST	373,357	**0.7%**	**2.8%**	141,290	51.4%	**-0.6%**	**0.8%**
2	2	ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	101,744	**1.1%**	**5.0%**	43,923	16.0%	**0.0%**	**3.5%**
3	3	ANTIPARKINSONISM DRUGS,ANTICHOLINERGIC	54,085	**-1.8%**	**-1.8%**	21,194	7.7%	**-1.9%**	**-3.3%**
4	7	OPIOID WITHDRAWAL THERAPY AGENTS, OPIOID-TYPE	41,888	**5.4%**	**30.4%**	13,016	4.7%	**4.8%**	**25.1%**
5	4	BIPOLAR DISORDER DRUGS	27,195	**-1.9%**	**-1.7%**	11,200	4.1%	**-2.5%**	**-4.1%**
6	5	INSULINS	21,597	**-1.4%**	**-6.2%**	10,638	3.9%	**-4.6%**	**-6.7%**
7	6	ANTIVIRALS, HIV-SPEC, NUCLEOSIDE-NUCLEOTIDE ANALOG	22,817	**-4.4%**	**-4.7%**	10,481	3.8%	**-3.4%**	**-1.5%**
8	10	ARV-NUCLEOSIDE,NUCLEOTIDE RTI,INTEGRASE INHIBITORS	21,448	**11.4%**	**53.6%**	8,851	3.2%	**9.2%**	**56.6%**
9	8	ANTIPSYCHOTICS,DOPAMINE ANTAGONISTS,BUTYROPHENONES	22,370	**-5.2%**	**-3.4%**	8,714	3.2%	**-3.5%**	**-2.9%**
10	14	OPIOID ANTAGONISTS	11,076	**27.0%**	**87.3%**	8,563	3.1%	**33.7%**	**110.6%**
11	9	ANTICONVULSANTS	16,346	**-2.1%**	**0.4%**	6,670	2.4%	**-3.8%**	**-2.0%**
12	11	ANTIVIRALS,HIV-1 INTEGRASE STRAND TRANSFER INHIBTR	11,032	**-5.0%**	**-11.5%**	4,637	1.7%	**-5.4%**	**-9.0%**
13	12	ANTIPSYCHOTICS,PHENOTHIAZINES	11,878	**-2.7%**	**-6.5%**	4,406	1.6%	**-4.4%**	**-9.3%**
14	13	ANTIRETROVIRAL-NRTIS AND INTEGRASE INHIBITORS COMB	9,731	**-3.4%**	**-9.5%**	3,881	1.4%	**-5.3%**	**-9.7%**
15	16	ANTIVIRALS, HIV-SPEC, NON-PEPTIDIC PROTEASE INHIB	7,521	**-8.7%**	**-17.7%**	3,068	1.1%	**-7.9%**	**-16.7%**
16	15	ARTV NUCLEOSIDE,NUCLEOTIDE,NON-NUCLEOSIDE RTI COMB	7,390	**-5.7%**	**-22.5%**	3,004	1.1%	**-7.1%**	**-22.6%**
17	18	OPIOID ANALGESICS	5,822	**1.1%**	**-3.0%**	2,986	1.1%	**0.3%**	**-5.0%**
18	19	ANTIVIRALS, HIV-SPECIFIC, NUCLEOTIDE ANALOG, RTI	4,636	**-5.7%**	**-26.0%**	2,098	0.8%	**-5.6%**	**-25.0%**
19	17	ANTIVIRALS, HIV-SPECIFIC, PROTEASE INHIBITORS	5,097	**-12.3%**	**-36.1%**	2,081	0.8%	**-11.6%**	**-35.3%**
20	21	ANTICONVULSANT - BENZODIAZEPINE TYPE	4,504	**-4.8%**	**4.5%**	2,003	0.7%	**-9.8%**	**3.8%**

Tables 6.1-6.3. Top 20 Fee-for-Service Drugs in the Medi-Cal Population.

These tables present the utilization of the top 20 drugs in the Medi-Cal Fee-for-Service program, by **total utilizing beneficiaries.** The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization for these drugs. The prior-year quarter ranking of each drug is listed for reference.

Table 6.1: Top 20 Fee-for-Service Drugs by *Total Utilizing Beneficiaries* for the Entire Medi-Cal Population

Rank	Last Year Rank	Drug Description	Current Quarter 2018 Q4 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries from *Prior Quarter*	% Change Utilizing Total Utilizing Beneficiaries *Prior-Year Quarter*
1	1	IBUPROFEN	77,903	**3.1%**	**-7.2%**	68,795	8.7%	**2.7%**	**-7.7%**
2	2	QUETIAPINE FUMARATE	139,064	**0.8%**	**1.6%**	52,817	6.7%	**-0.8%**	**-0.2%**
3	3	ARIPIPRAZOLE	103,831	**0.4%**	**3.0%**	44,682	5.7%	**-0.9%**	**1.5%**
4	4	ASPIRIN	48,534	**-4.4%**	**-17.1%**	33,181	4.2%	**-4.8%**	**-17.1%**
5	7	RISPERIDONE	81,791	**0.1%**	**-0.7%**	32,601	4.1%	**-1.0%**	**-2.4%**
6	5	AMOXICILLIN	32,812	**10.8%**	**-13.6%**	30,175	3.8%	**11.0%**	**-13.9%**
7	9	OLANZAPINE	79,685	**1.6%**	**4.8%**	30,170	3.8%	**0.6%**	**2.8%**
8	6	ALBUTEROL SULFATE	42,424	**22.2%**	**-11.8%**	29,446	3.7%	**25.2%**	**-14.8%**
9	8	FERROUS SULFATE	36,028	**-8.8%**	**-10.1%**	26,857	3.4%	**-9.2%**	**-10.4%**
10	13	METFORMIN HCL	39,647	**-1.9%**	**0.0%**	26,354	3.3%	**-1.5%**	**1.0%**
11	10	DOCUSATE SODIUM	37,934	**-3.8%**	**-9.9%**	25,638	3.3%	**-3.8%**	**-10.3%**
12	11	LORATADINE	37,173	**1.3%**	**-11.8%**	24,717	3.1%	**3.6%**	**-11.9%**
13	14	CEPHALEXIN	23,503	**-8.6%**	**-5.9%**	22,125	2.8%	**-8.8%**	**-5.6%**
14	12	HYDROCODONE/ ACETAMINOPHEN	25,968	**-11.6%**	**-20.9%**	21,419	2.7%	**-12.1%**	**-21.0%**
15	15	BENZTROPINE MESYLATE	54,655	**-0.5%**	**-0.7%**	21,413	2.7%	**-1.0%**	**-2.3%**
16	16	LISINOPRIL	31,081	**-1.0%**	**-2.2%**	20,883	2.7%	**-0.7%**	**-0.7%**
17	19	ATORVASTATIN CALCIUM	29,985	**1.7%**	**11.7%**	19,786	2.5%	**2.3%**	**12.0%**
18	17	AZITHROMYCIN	19,655	**33.3%**	**-12.6%**	17,970	2.3%	**34.4%**	**-13.7%**
19	21	LURASIDONE HCL	40,572	**0.9%**	**5.2%**	16,943	2.2%	**-0.5%**	**3.3%**
20	20	METRONIDAZOLE	16,404	**-5.2%**	**-12.2%**	15,399	2.0%	**-4.8%**	**-12.1%**

Table 6.2: Top 20 Fee-for-Service Drugs by *Total Utilizing Beneficiaries* for the Medi-Cal FFS Population Only

Rank	Last Year Rank	Drug Description	Current Quarter 2018 Q4 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries from *Prior Quarter*	% Change Utilizing Total Utilizing Beneficiaries *Prior-Year Quarter*
1	1	IBUPROFEN	76,925	3.3%	-6.7%	67,951	15.3%	3.0%	-7.1%
2	2	ASPIRIN	47,562	-4.4%	-17.1%	32,680	7.3%	-4.8%	-17.0%
3	3	AMOXICILLIN	32,191	11.1%	-13.2%	29,696	6.7%	11.2%	-13.3%
4	4	ALBUTEROL SULFATE	39,433	23.2%	-12.5%	28,133	6.3%	26.3%	-14.9%
5	6	FERROUS SULFATE	34,732	-8.4%	-7.3%	26,004	5.8%	-8.7%	-6.7%
6	5	DOCUSATE SODIUM	37,359	-3.9%	-9.4%	25,254	5.7%	-3.6%	-9.4%
7	9	METFORMIN HCL	37,428	-2.3%	0.8%	25,193	5.7%	-1.5%	1.7%
8	7	LORATADINE	36,579	1.3%	-11.9%	24,397	5.5%	3.7%	-11.7%
9	10	CEPHALEXIN	22,317	-9.0%	-4.7%	21,020	4.7%	-9.0%	-4.4%
10	8	HYDROCODONE/ ACETAMINOPHEN	25,457	-11.8%	-20.3%	20,982	4.7%	-12.1%	-20.5%
11	11	LISINOPRIL	29,940	-1.1%	-1.7%	20,241	4.6%	-0.4%	-0.1%
12	14	ATORVASTATIN CALCIUM	29,608	0.4%	12.4%	19,547	4.4%	1.9%	12.9%
13	13	AZITHROMYCIN	15,665	43.3%	-16.3%	14,388	3.2%	44.7%	-17.4%
14	12	ACETAMINOPHEN	15,348	18.9%	-22.9%	14,373	3.2%	17.5%	-22.0%
15	15	FOLIC ACID	24,141	-4.7%	-5.7%	13,870	3.1%	-4.9%	-4.6%
16	17	AMLODIPINE BESYLATE	20,453	-2.0%	0.2%	13,189	3.0%	-1.2%	2.6%
17	16	PROMETHAZINE/ DEXTROMETHORPHAN	14,657	90.0%	-9.0%	12,987	2.9%	93.9%	-9.2%
18	20	PRENATAL VITAMIN NO 95	14,557	10.2%	98.9%	12,971	2.9%	9.6%	100.6%
19	18	GABAPENTIN	22,091	-2.7%	1.5%	12,837	2.9%	-2.8%	1.1%
20	19	LEVOTHYROXINE SODIUM	20,838	-2.5%	-4.6%	12,212	2.7%	-0.7%	-2.4%

Table 6.3: Top 20 Fee-for-Service Drugs by *Total Utilizing Beneficiaries* for the Medi-Cal MCP Population Only

Rank	Last Year Rank	Drug Description	Current Quarter 2018 Q4 Total Paid Claims	% Change from *Prior Quarter*	% Change from *Prior-Year Quarter*	Current Quarter Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Total Utilizing Beneficiaries from *Prior Quarter*	% Change Utilizing Total Utilizing Beneficiaries *Prior-Year Quarter*
1	1	QUETIAPINE FUMARATE	127,953	0.8%	1.9%	48,601	17.7%	-0.7%	-0.2%
2	2	ARIPIPRAZOLE	95,934	0.7%	3.5%	41,363	15.1%	-0.4%	2.0%
3	3	RISPERIDONE	72,731	-0.2%	-0.3%	29,135	10.6%	-1.0%	-1.9%
4	4	OLANZAPINE	71,664	1.0%	4.9%	27,129	9.9%	0.2%	2.8%
5	5	BENZTROPINE MESYLATE	50,040	-1.0%	-0.4%	19,617	7.1%	-1.2%	-2.1%
6	6	LURASIDONE HCL	38,156	0.7%	5.2%	15,938	5.8%	-0.9%	3.3%
7	7	LITHIUM CARBONATE	26,880	-1.9%	-1.8%	11,066	4.0%	-2.6%	-4.3%
8	8	BUPRENORPHINE HCL/ NALOXONE HCL	35,562	5.9%	33.3%	10,631	3.9%	5.1%	27.0%
9	10	PALIPERIDONE PALMITATE	18,539	4.5%	18.5%	7,696	2.8%	2.3%	16.2%
10	9	HALOPERIDOL	17,750	-6.8%	-5.7%	6,822	2.5%	-5.6%	-6.0%
11	12	EMTRICITABINE/ TENOFOVIR (TDF)	12,343	-1.4%	0.8%	6,250	2.3%	-0.1%	4.9%
12	11	ZIPRASIDONE HCL	15,265	-2.4%	-6.5%	5,588	2.0%	-3.9%	-8.7%
13	19	NALOXONE HCL	5,432	70.9%	245.1%	5,168	1.9%	69.8%	251.6%
14	13	ELVITEG/COB/EMTRI/ TENOF ALAFEN	11,039	-6.4%	-11.2%	4,521	1.7%	-6.6%	-9.4%
15	16	INSULIN LISPRO	9,143	-0.7%	-2.1%	4,232	1.5%	-4.1%	-3.3%
16	14	EMTRICITABINE/ TENOFOV ALAFENAM	10,470	-7.8%	-10.5%	4,229	1.5%	-7.8%	-9.6%
17	15	INSULIN GLARGINE, HUM.REC.ANLOG	7,447	-3.3%	-12.5%	4,027	1.5%	-5.8%	-11.3%
18	N/A	BICTEGRAV/EMTRICIT/ TENOFOV ALA	9,616	45.9%	N/A	3,979	1.5%	38.8%	N/A
19	17	ABACAVIR/DOLUTEGRAVIR/ LAMIVUDI	9,731	-3.4%	-9.5%	3,881	1.4%	-5.3%	-9.7%
20	18	DOLUTEGRAVIR SODIUM	8,946	-4.5%	-7.4%	3,705	1.4%	-4.7%	-5.4%

APPENDIX B: Definition of terms.

Adjudicate: To pay or deny drug claims after evaluating the claim for coverage requirements

Beneficiary: A person who has been determined eligible for Medi-Cal, as according to the California Code of Regulations 50024

Eligible beneficiary: A Medi-Cal beneficiary that qualifies for drug benefits

Quarter: One fourth, ¼, 25% or .25 of a year measured in months.

Reimbursement: The reimbursement paid to Medi-Cal pharmacy providers for legend and nonlegend drugs dispensed to Medi-Cal Fee-for-Service (FFS) beneficiaries. Reimbursement is determined in accordance with CA Welfare and Institutions Code Section 14105.45(b)(1).

Drug therapeutic category: Drug therapeutic categories are grouping of drugs at various hierarchy levels and characteristics that may be similar in chemical structure, pharmacological effect, clinical use, indications, and/or other characteristics of drug products.

Utilizing beneficiary: A Medi-Cal beneficiary with at least one prescription filled during the measurement period

MEDI-CAL DRUG USE REVIEW (DUR) PROGRAM
2018 BIENNIAL EVALUATION REPORT – PART I

Executive Summary

The purpose of the educational intervention component of DUR is to improve the quality and cost-effectiveness of prescribing and dispensing practices for Medi-Cal beneficiaries. Educational interventions include ongoing dissemination of clinically important information through the Medi-Cal provider bulletin process.

DUR educational articles are published in provider bulletins and posted on the DUR: Educational Articles page on the DUR website. At least two years after publication, each DUR educational article is reviewed again in a systematic way in order to evaluate any change over time. This biennial evaluation report analyzes each article using the following template:

- Background
- Purpose
- Data Criteria and Findings
- Analysis
- Limitations
- Research/Policy Recommendations
- Clinical Recommendations

Many factors may influence the prescribing and dispensing practices of Medi-Cal providers, making it difficult to accurately measure the full impact of the educational articles. Such factors may include, but are not limited to, the following:

- Changes and updates to treatment guidelines and recommendations
- Beneficiary expectations and requests and healthcare habits and behavior
- Direct-to-consumer advertising
- Provider training and experience
- Anecdotal experience
- Provider resistance

The purpose of DUR educational articles is to apprise Medi-Cal providers and pharmacies of current treatment guidelines and recommendations on drugs, disease states, and medical conditions. These articles contain valuable information that is

effective when used as a part of an overall campaign to disseminate timely and needed information to providers and pharmacies. The following recommendations may help to improve accessibility, reach, and interest of educational articles to the Medi-Cal provider and pharmacy community:

- Continue to distribute articles through normal publication channels, but also send articles separate and independent from the bulletin, in order to increase visibility.
- Distribute article links to medical and pharmaceutical organizations/associations for distribution to their members or publications in journals and/or bulletins.
- Encourage prescribers and pharmacists to sign up for distribution of DUR articles via the Medi-Cal Subscription Service (MCSS).
- Facilitate continuing medical education (CME) and/or continuing education (CE) opportunities to prescribers and pharmacists related to article content
- Incorporate case studies into articles.
- Package articles with other collateral materials for distribution through various media channels such as posters, postcard mailings and flyers that highlight the recommendations of each the article.
- Disseminate shorter educational alerts that highlight relevant and important topics that can be published with greater frequency.
- When appropriate, disseminate lay versions of articles to beneficiaries to promote physician uptake and set beneficiary expectations.
- Continue to support the direct link between articles and retrospective DUR educational outreach to prescribers and pharmacists.
- Increase understanding of prospective DUR alert methodology, by using articles to focus on drug therapy problems that are frequently overridden at the pharmacy level.
- Include patient-specific profiles for educational outreach where the primary objective is an improvement in the quality of care.
- Use provider-specific profiles for educational outreach where the primary objective is an improvement in the quality of prescribing.
- Use pharmacy-specific profiles for educational outreach where the primary objective is an improvement in the quality of dispensing.

The 2018 report provides detailed evaluations of the following DUR educational articles, which were published between October 2014 and September 2016:

- Clinical Review: Use of Nicotine Replacement Therapy for Smoking Cessation – October 2014
- Alert: Folic Acid Awareness Week is January 4th – 10th, 2015 – December 2014
- Alert: Depression Among Perinatal Women is Overlooked and Undertreated – January 2015

- Improving the Quality of Care: Methotrexate Use and Folate Supplementation – February 2015
- Drug Safety Communication: Varenicline and Alcohol Use – March 2015
- Improving the Quality of Care: Antipsychotic Use in Children and Adolescents – March 2015
- Drug Safety Communication: NSAIDs Increase Chance of Heart Attack or Stroke – August 2015
- 2015 Immunization Updates: Influenza, HPV, MenB, PVC13, and SB 277 – September 2015
- Clinical Review: Morphine Equivalent Daily Dose to Prevent Opioid Overuse – September 2015
- Clinical Review: Concomitant Use of Anticholinergics and Antipsychotics – November 2015
- Alert: California Upgrades Prescription Drug Monitoring Program to CURES 2.0 – January 2016
- Drug Safety Communication: Saxagliptin, Alogliptin and Risk of Heart Failure – April 2016
- Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects – April 2016
- Drug Safety Communication: New Safety Warnings Added to Prescription Opioids – April 2016
- Clinical Review: The Treatment of Opioid Addiction with Buprenorphine – August 2016
- 2016 Immunization Updates: Influenza, Meningococcal, Tdap, Hib, Rotavirus – September 2016

In order to maximize the time the Board will have to review this report, the 2018 Biennial Report has been split into two parts. The first eight articles will be presented at the February 2019 meeting (Part I) and the remaining eight articles will be presented at the May 2019 meeting (Part II).

Biennial Review: Evaluation of Educational Articles – Part I

1. Clinical Review: Use of Nicotine Replacement Therapy for Smoking Cessation – October 2014

- **Background:** Nicotine replacement therapy (NRT) aids in smoking cessation by delivering nicotine to reduce the severity of nicotine withdrawal symptoms. There is strong evidence supporting the effectiveness of NRT to treat tobacco dependence and aid in smoking cessation and clinical trial data show all commercially available NRT formulations increase the odds of quitting approximately 1.5 to 2-fold, regardless of setting. Furthermore, some data suggest that NRT combination therapy, which includes the patch once daily plus a short-acting NRT as needed, is more effective than single agent NRT. A review of pharmacy claims data found that between August 1, 2013, and July 31, 2014, only 33 Medi-Cal fee-for-service beneficiaries had paid claims for NRT combination therapy. However, prior to July 1, 2014, an approved *Treatment Authorization Request* was required for gum and lozenge formulations of NRT and half of these beneficiaries (n=16) had paid claims for NRT combination therapy in July 2014, after these restrictions were removed.

- **Purpose:** The purpose of this biennial review is to review if there have been any pharmacy policy updates regarding NRT since the article was published. In addition, data from the Medi-Cal fee-for-service population were reviewed to determine if there have been any changes in the total number of Medi-Cal fee-for-service beneficiaries that initiated NRT combination therapy.

- **Data Criteria and Findings:** The biennial review followed the same criteria as the published article. All paid pharmacy claims for NRT with dates of service between October 1, 2017, and September 30, 2018, were reviewed.

Medi-Cal fee-for-service population	Article data: 08/01/13 – 07/31/14	Biennial review data: 08/01/17 – 07/31/18	Percent change
Number of beneficiaries with at least one paid claim for NRT	4,439	7,263	***64%***
Number of beneficiaries initiating NRT combination therapy	33	298	***803%***

Effective January 25, 2016, pursuant to Section 1746.2 of the *California Code of Regulations*, pharmacists are now authorized to furnish NRT products approved

by the U.S. Food and Drug Administration (FDA) for use by prescription in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. A DUR educational article that reviewed pharmacist furnishing of NRT was published in March 2018. This article found that while the regulation allowing pharmacists in California to furnish NRT became effective over two years ago, claims data for the Medi-Cal fee-for-service program showed limited adoption among California pharmacists (less than 1% of all claims for NRT were furnished by pharmacists). However, this same article found that there was a much higher rate of combination NRT among pharmacist-furnished paid claims (24% vs. 3%).

- **Analysis:** This biennial review shows that paid claims for NRT have increased significantly since the original article was published, with use of NRT increasing by 64%. Since authorization restrictions on the gum and lozenge formulations of NRT were removed, initiation of NRT combination therapy increased by 803%, with hundreds of Medi-Cal fee-for-service beneficiaries initiating smoking cessation efforts using recommended first-line treatment in the past year alone. While legislative efforts to allow furnishing of NRT by pharmacists may also be contributing to the increase in use of NRT combination therapy, the data show opportunities for improvement regarding the total number of pharmacists and pharmacies that furnish NRT to Medi-Cal beneficiaries.

- **Limitations:** These data do not include any pharmacy claims that were not processed as claims through the Medi-Cal program.

- **Research/Policy Recommendations:**
    1. Continue to educate providers and pharmacists about the importance of identifying and documenting tobacco use status for every patient at every visit. Tobacco dependence often requires repeated interventions and multiple quit attempts.
    2. Continue to disseminate DUR research findings to the California Tobacco Control Branch, in order to identify potential funding opportunities and areas for collaboration.
    3. Continue to promote and support pharmacist furnishing of NRT.
    4. Work with Medi-Cal Managed Care Plans (MCPs) to develop a less restrictive and more consistent policy in regards to the drugs that are covered for tobacco cessation. While MCPs are contractually required to cover all FDA-approved tobacco cessation medications for adults who use tobacco products, they are only required to cover one FDA-approved tobacco cessation medication without authorization.

- **Clinical Recommendations:**
    1. All health care providers should identify and document tobacco use status for every patient at every visit.
    2. All health care providers should encourage active tobacco users to quit at every encounter, as multiple attempts are often required to treat tobacco dependence.
    3. All health care providers should promote the use combination NRT therapy, which has been shown to be more effective at improving quit rates than NRT monotherapy.
    4. All health care providers should refer patients to the California Smokers' Helpline at 1-800-NO-BUTTS, which includes free telephone counseling, text messaging, and online self-help resources available in multiple languages.
    5. All health care providers should promote the Great American Smokeout, a social campaign by the American Cancer Society held every year on the third Thursday of November. All health care providers are encouraged to promote this event and assist patients with planning their quit date.
    6. All pharmacists should review the §1746.2 Protocol for Pharmacists Furnishing Nicotine Replacement Products and complete the necessary training in order to furnish NRT products.

2. Alert: Folic Acid Awareness Week is January 4th – 10th, 2015 – December 2014

- **Background:** Research has shown that a daily intake of 0.4mg (400 µg) of folic acid prior to conception can reduce the risk of having an infant born with a neural tube defect (NTD) such as spina bifida or anencephaly by approximately 80%. Both the United States Public Health Service (USPHS) and the Centers for Disease Control and Prevention (CDC) recommend that all women between 15 and 45 years of age should consume 0.4 mg folic acid daily because half of all U.S. pregnancies are unplanned, and these birth defects occur very early in pregnancy (three to four weeks after conception), before most women know they are pregnant. A review of folic acid supplementation within the Medi-Cal fee-for-service program found that only 9% of female Medi-Cal fee-for-service beneficiaries between 15 and 45 years of age had at least one paid claim for folic acid during a one-year time period (between October 1, 2013, and September 30, 2014). This article was published to highlight the importance of folic acid and increase folic acid use in the Medi-Cal fee-for-service population.

- **Purpose:** The purpose of this biennial review is to review the use of folic acid supplementation and to describe relevant policy changes, if any. Data from the Medi-Cal fee-for-service population were reviewed to determine if there have been any changes in the percentage of female Medi-Cal fee-for-service beneficiaries between 15 and 45 years of age with at least one paid claim for folic acid during a one-year time period.

- **Data Criteria and Findings:** All paid pharmacy claims for folic acid with dates of service between October 1, 2017, and September 30, 2018, were reviewed for female Medi-Cal fee-for-service beneficiaries between 15 and 45 years of age.

Medi-Cal fee-for-service population	Article data: 10/01/13 – 09/30/14	Biennial review data: 10/01/17 – 09/30/18	Percent change
Percentage of females between 15 and 45 years of age with at least one paid claim for folic acid during a one-year period	9%	9%	***0%***

In 2017, the U.S. Preventive Services Task Force (USPSTF) reviewed and assessed new evidence on the benefits and harms of folic acid supplementation, and reaffirmed their 2009 recommendation that all women who are planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400-800 µg) of folic acid. Folic acid awareness week continues to be held annually during the second week of January.

- **Analysis:** This biennial review shows that the percentage of female Medi-Cal fee-for-service beneficiaries between 15 and 45 years of age with at least one paid claim for folic acid during a one-year time period has remained unchanged since the original article was published in 2014.

- **Limitations:** These data do not include all potential sources of folic acid, including dietary folic acid and folic acid supplements processed outside of the Medi-Cal pharmacy claims system.

- **Research/Policy Recommendations:**
    1. Continue to educate female Medi-Cal beneficiaries of childbearing age about the importance of meeting daily folic acid guidelines.
    2. Promote that folic acid supplementation is a Medi-Cal pharmacy benefit for female fee-for-service beneficiaries ages 14 through 45 years, in order to prevent neural tube defects in current and future pregnancies.

- **Clinical Recommendations:**
    1. All health care providers should recommend 0.4 mg folic acid daily to all women between 15 and 45 years of age.

3. Alert: Depression Among Perinatal Women is Overlooked and Undertreated – January 2015

- **Background:** According to a study published in the November 2014 edition of *CNS Spectrums,* perinatal women enrolled in the Medi-Cal fee-for-service program are less likely to be diagnosed with depression than non-pregnant women, even though pregnancy increases the risk of depression in women. The authors of the study analyzed three years of data from women continuously enrolled in the Medi-Cal fee-for-service program and found that even when pregnant women were diagnosed with depression, fewer than half received any treatment, versus 72 percent receiving treatment in a non-pregnant control group. Women suffering from postpartum depression were similarly undertreated. Specific demographic factors predicting a lower probability of depression detection and treatment included women who were of Hispanic ethnicity, under 25 years of age, and/or residing in a rural setting.

- **Purpose:** The purpose of this biennial review is to review if there have been any relevant updates to Medi-Cal pharmacy policy or research on maternal mental health.

- **Data Criteria and Findings:** A comprehensive set of laws addressing maternal mental health was signed by Governor Brown in September 2018, after a report on the impact of untreated maternal mental health disorders was issued to the state legislature last year. The new laws underscore the importance of addressing maternal mental health disorders as a core component of the delivery of quality maternity care and support the healthy development of our infants and children. These bills are the first comprehensive maternal mental health bill package in the nation, and include:
    - **AB 3032,** Hospital Maternal Mental Health: Starting January 1, 2020, requires hospitals to provide maternal mental health training to clinical staff who work with pregnant and postpartum women, and to educate women and families about the signs and symptoms of maternal mental health disorders as well as any local treatment options.
    - **AB 2193,** Maternal Mental Health Screening and Support: Becomes effective July 1, 2019, and requires obstetric providers to confirm screening for maternal depression has occurred or to screen women directly, at least once during pregnancy or the postpartum period. It also requires private and public health plans and health insurers to create maternal mental health programs.

- **AB 1893,** Maternal Mental Health Federal Funding: Was signed by the governor on July 20, 2018 and requires the state Department of Public Health to apply for federal funding provided through the Bringing Postpartum Depression Out of the Shadows Act (part of the 21st Century Cures Act).

- **Analysis:** This biennial review highlights several legislative efforts to address maternal mental health disorders since the original article was published.

- **Limitations:** None.

- **Research/Policy Recommendations:** None.
  1. Continue to support research on ways to overcome barriers to maternal mental health treatment, in order to increase access to treatment and receipt of care.
  2. Conduct research specific to perinatal Medicaid beneficiaries to better understand prevalence of screening and treatment for maternal mental health.
  3. Continue to monitor the impact of legislative efforts to improve maternal mental health outcomes.
  4. Promote screening efforts for maternal depression and evaluate screening prevalence before and after the law requiring screening is implemented.

- **Clinical Recommendations:**
  1. Health care providers should recognize that maternal mental health treatment must take into account unique cultural experiences and should adjust accordingly to fit each patient's needs.
  2. Health care providers should screen for depression and anxiety in a way that engages the patient and ensures that she understands the condition and treatment options.
  3. Health care providers should complete a mental health assessment of some type at all prenatal and postpartum visits in order to assess response trends and catch changes in depressive symptoms. This includes screening mothers during scheduled pediatric visits.

4. Improving the Quality of Care: Methotrexate Use and Folate Supplementation – February 2015

- **Background:** While there is no cure for rheumatoid arthritis (RA), early referral, diagnosis, and initiation of treatment can curb or slow disease progression. The American College of Rheumatology (ACR) currently recommends initiating treatment with disease-modifying antirheumatic drugs (DMARDs) within three months of diagnosis, barring contraindications, inactive disease, or patient refusal. While there are several DMARDs approved by the United States Food and Drug Administration (FDA) for the treatment of RA, methotrexate is used by most rheumatologists as a first line drug of choice due to a long history of documented efficacy, an established safety profile, lower cost, and the availability of long-term follow-up data. Because methotrexate blocks folate metabolism, some patients who take methotrexate may experience side effects resulting from a folate deficiency, including mouth ulcers, gastrointestinal problems such as nausea or abdominal pain, hepatic dysfunction, or problems with blood cell production. These side effects are sometimes bad enough that patients will discontinue treatment with methotrexate. While there is no definitive answer regarding the optimal dose of folate supplementation for patients with RA who are being treated with methotrexate, there is consensus that concomitant use of folic acid or folinic acid may reduce toxic effects of methotrexate and improve adherence to therapy and compliance. The original article found that only 40 percent of Medi-Cal fee-for-service beneficiaries being treated with methotrexate for rheumatoid arthritis had a paid pharmacy claim for folic acid.

- **Purpose:** The purpose of this biennial review is to evaluate if there have been updates to clinical guidelines regarding the concomitant use of folic acid since the original DUR educational article was published in February 2015. In addition, data from the Medi-Cal fee-for-service population were reviewed to determine if there have been any changes in the percentage of Medi-Cal fee-for-service beneficiaries taking methotrexate for RA that have concomitant paid claims for folic acid supplements.

- **Data Criteria and Findings:** For the biennial review, the same inclusion/exclusion criteria as the published article were followed:
    1. Inclusion criteria:
        i. Continuous eligibility for the Medi-Cal FFS program between October 1, 2017 and September 30, 2018 (the measurement year).
        ii. At least one paid pharmacy claim for methotrexate during the measurement year

iii. Primary ICD-9-CM diagnosis code for arthritis or other rheumatic conditions, as defined by the National Arthritis Data Workgroup (NADW)

2. Exclusion criteria:
   i. Beneficiaries who were dually eligible for Medi-Cal and Medicare.

Medi-Cal fee-for-service population	Article data: 10/01/13 – 09/30/14	Biennial review data: 10/01/17 – 09/30/18	Percent change
Beneficiaries identified that met inclusion and exclusion criteria for the study population	***1,546***	***143***	***-90.8%***
Percentage of study population with ≥1 paid claim for folic acid during the measurement year	40%	10%	***-30.0%***

A 2018 systematic review published in the Journal of Clinical Rheumatology (Liu, 2018) concluded that folate supplementation can reduce the incidence of hepatotoxicity and gastrointestinal side effects of methotrexate in patients with rheumatoid arthritis and can also reduce patient withdrawal from methotrexate treatment. The 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis continues to recommend methotrexate as the preferred initial DMARD for most early RA patients, as well as concomitant use of folate supplementation for patients initiating methotrexate treatment.

- **Analysis:** While the 2019 update of the American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis is still in progress, there have been no changes thus far to the recommendation for folate supplementation with methotrexate since the original article was published. Given this, the reason for the decrease observed in the use of folic acid since the original article was published is not clear. A 2016 study conducted in the Veterans Health Administration (VHA) found that rheumatologists were much more likely to prescribe folic acid than other providers.

- **Limitations:** These data do not include all potential sources of folic acid, including dietary folic acid and folic acid supplements processed outside of the Medi-Cal pharmacy claims system.

- **Research/Policy Recommendations:**
    1. Continue to educate patients and providers about cost-effective first-line treatments.
    2. Continue to promote options for improving adherence to treatment regimens, including standardizing workflow for co-prescribing of methotrexate and folic acid.
    3. Follow updates to clinical guidelines, as they become available.

- **Clinical Recommendations:**
    1. Health care providers should recommend folate supplementation with the initiation of methotrexate therapy, in order to improve the chances of patient adherence to methotrexate treatment by mitigating some of the side effects associated with methotrexate therapy.

5. Drug Safety Communication: Varenicline and Alcohol Use – March 2015

- **Background:** On March 9, 2015, the FDA issued a warning that varenicline can change the way people react to alcohol, with a recommendation that patients taking varenicline should decrease the amount of alcohol they drink until they become aware of how varenicline affects their ability to tolerate alcohol. The FDA warned that some patients may experience decreased tolerance to alcohol, increased drunkenness, unusual or aggressive behavior, or memory loss, and stated there have been rare reports of seizures in patients treated with varenicline.

- **Purpose:** The purpose of this biennial review is to review the FDA safety communications on varenicline and to describe relevant updates, if any.

- **Data Criteria and Findings:** On December 16, 2016, the FDA published an updated Drug Safety Communication entitled, "FDA revises description of mental health side effects of the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) to reflect clinical trial findings." The FDA based this revision on the results of a large clinical trial, which had been required by the FDA after the *Boxed Warning* was added to the labels in 2009. The results of the trial prompted the FDA to issue this updated communication and to remove the *Boxed Warning* for serious mental health side effects from varenicline and the language describing the serious mental health side effects seen in patients quitting smoking from the *Boxed Warning* on bupropion.

- **Analysis:** The biennial review found the FDA revised the *Boxed Warning* based on updated data from a large clinical trial, which determined the risk of serious side effects on mood, behavior, or thinking with varenicline and bupropion was lower than previously suspected. While the clinical trial concluded the risk of mental health side effects is still present, most people who had these side effects did not have serious consequences such as hospitalization. The results of the trial confirmed that the benefits of stopping smoking outweigh the risks of these medicines.

- **Limitations:** None.

- **Research/Policy Recommendations:**
    1. Move the original article into the "Archives" section so it no longer appears on the DUR educational article page.

2. Continue to monitor FDA communications regarding varenicline and bupropion.

- **Clinical Recommendations:**
    1. Health care providers should counsel patients about the benefits of stopping smoking and how they can get help to quit, and discuss the benefits and risks of using medicines to help them quit smoking.
    2. Health care providers should make sure that patients taking varenicline or bupropion know to call them right away if they notice any side effects on their mood, behavior, or thinking.

6. Improving the Quality of Care: Antipsychotic Use in Children and Adolescents – March 2015

- **Background:** This bulletin evaluated the following two new measures that had been added to the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS®) for 2015:
    1. Metabolic Monitoring for Children and Adolescents on Antipsychotics (APM), which assesses the percentage of children and adolescents who have ongoing use of antipsychotic medications and metabolic testing during the measurement year
    2. Use of Multiple Concurrent Antipsychotics in Children and Adolescents (APC), which assesses the percentage of children and adolescents who were taking two or more concurrent antipsychotics for at least 90 days during the measurement year

  Of the 6,013 children and adolescents identified with at least two paid claims for an antipsychotic medication during the measurement year, only 37.4% had paid claims for metabolic monitoring during that same time period (both blood glucose or HbA1C and LDL-C or cholesterol). Among the 5,375 children and adolescents with at least 90 consecutive days of antipsychotic medication treatment during the measurement year, a total of 306 (5.7%) were taking two or more concurrent antipsychotics for at least 90 days during the measurement year.

- **Purpose:** The purpose of this biennial review is to review if there were any updates to pharmacy policy, clinical guidelines, or measures regarding the use of antipsychotics in children and adolescent since the original DUR alert was published in March 2015. In addition, data from the Medi-Cal fee-for-service population were reviewed to determine if there have been any changes in the APM and APC measures since the original article was published.

- **Data Criteria and Findings:** Effective October 1, 2014, any use of antipsychotic medications for Medi-Cal beneficiaries 0 – 17 years of age required an approved *Treatment Authorization Request* (TAR). The original article used the year before this policy change as the measurement year to serve as a baseline for future analyses. In August 2016, the DUR program completed an evaluation of pharmacy and medical claims data during the year following the implementation of the TAR requirement, in order to determine the impact of the policy change on the Medi-Cal fee-for-service population. To account for the transition period while the policy was being implemented, the measurement year for the analyses was calendar year 2015, in order to allow three months for the implementation of the

new policy. Results from this analysis are included in the table below for an additional comparison.

For the biennial review, the same inclusion/exclusion criteria as the published article were followed:

1. Inclusion criteria:
    i. Continuous eligibility for the Medi-Cal FFS program between October 1, 2017 and September 30, 2018 (the measurement year)
    ii. Between 1 and 17 years of age as of September 30, 2018
    iii. At least one paid pharmacy claim for an antipsychotic medication during the measurement year
2. Exclusion criteria:
    i. Beneficiaries who were dually-eligible for Medi-Cal and Medicare

Medi-Cal fee-for-service population	Article data: 10/01/13 – 09/30/14	Policy impact data: 01/01/15 – 12/31/15	Biennial review data: 10/01/17 – 09/30/18	Percent change
Beneficiaries meeting the inclusion criteria with at least one paid pharmacy claim for an antipsychotic medication during the measurement year	***6,888***	***4,281***	***3,188***	***-53.7%***
Beneficiaries with two or more paid claims for antipsychotic medications during the measurement year	***6,013***	***3,717***	***2,442***	***-59.4%***
Percentage with at least one test for both blood glucose/HbA1C and LDL-C/cholesterol during the measurement year	***37.4%***	***38.9%***	***53.6%***	***16.2%***
Percentage with at least one test for blood glucose/HbA1C during the measurement year	***52.4%***	***52.0%***	***64.2%***	***12.2%***
Percentage with at least one test for LDL-C/cholesterol during the measurement year	***37.9%***	***39.4%***	***55.4%***	***17.5%***
Beneficiaries with at least 90 consecutive days of antipsychotic medication treatment during the measurement year	***5,375***	***3,445***	***2,017***	***-62.4%***
Percentage taking two or more concurrent antipsychotics for at least 90 days during the measurement year	***5.7%***	***6.6%***	***6.0%***	***0.3%***

The APM and APC measures continue to be included as HEDIS measures for 2019. Also, the original article referenced practice parameters published by the American Academy of Child & Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Starting in 2016, AACAP archived these documents and began work on Clinical Practice Guidelines, a new series of documents intended to address the assessment and treatment of child and adolescent psychiatric disorders. Antipsychotic medication is among the first Clinical Practice Guidelines that will be developed, pending completed Agency for Healthcare Research and Quality (AHRQ) reviews.

- **Analysis:** The rate of glucose or Hb1AC monitoring continues to be much greater than LDL-C or cholesterol monitoring. While there was improvement shown in the overall number of beneficiaries with metabolic testing, there still is an opportunity for outreach to providers who could raise the metabolic monitoring rate calculated in the HEDIS measure by ordering both tests at the same time. All metrics have improved since before the TAR policy and immediately following the implementation of the TAR policy. The calculated rate of 6.6% of Medi-Cal fee-for-service beneficiaries on multiple concurrent antipsychotic medications in the biennial review is slightly higher (an increase of less than 1%) than before the policy change, although this may be a result of the greater overall reduction in the denominator, as compared with the reduction in the numerator.

- **Limitations:** Clinical data are not available, including results of metabolic screening. Provider responses to the educational outreach mailing often included a description of healthy clinical markers as a reason for less frequent screening in this population, who may have additional challenges for completing recommended blood work.

- **Research/Policy Recommendations:**
    1. Continue to discuss opportunities for further evaluation of antipsychotic use in children and adolescents.
    2. Discuss merits of ongoing educational outreach to providers regarding metabolic monitoring.
    3. Discuss whether additional educational outreach to providers should be developed to target polypharmacy in children and adolescents, including reviews of drug classes other than antipsychotic medications.

- **Clinical Recommendations:**
    1. Health care professionals should consider classes of medications other than antipsychotics when treating behavioral problems and consider

referrals to psychotherapy, including family therapy, and/or a child psychiatry consultation before starting antipsychotic medications.

2. Antipsychotic dosing should follow the “start low and go slow” approach and seek to find the lowest effective dose that follows both the current scientific literature and the clinical response of the patient. Multiple clinical guidelines suggest that higher than approved dosages of antipsychotic medications should be avoided.
3. Multiple psychotropic medications or polypharmacy should be avoided whenever possible, especially in children and adolescents given the long-term consequences of such treatment is poorly understood.
4. Follow monitoring guidelines for antipsychotic medications and regularly evaluate patients for side effects and tolerability. At regular intervals, consider slow tapers of these medications if patient is generally stable.

7. Drug Safety Communication: NSAIDs Increase Chance of Heart Attack or Stroke – August 2015

- **Background:** The risk of heart attack and stroke with oral non-steroidal anti-inflammatory drugs (NSAIDs) was first described in 2005 in the *Boxed Warning* and *Warnings and Precautions* sections of the prescription drug labels. Since then, the FDA has continuously reviewed new safety information as it became available, including observational studies, a large combined analysis of clinical trials, and other scientific publications. On July 9, 2015, the FDA announced they would be strengthening an existing label warning that NSAIDs increase the chance of a heart attack or stroke, either of which can lead to death.

- **Purpose:** The purpose of this biennial review is to review if there were any warnings or actions by the FDA regarding NSAIDs since the original DUR alert was published in August 2015.

- **Data Criteria and Findings:** There were no additional FDA communications on this topic since the drug safety communication on July 9, 2015. Results from a recent systematic review published in The BMJ (Bally, 2017) state that taking any dose of NSAIDs for one week, one month, or more than a month was associated with an increased risk of myocardial infarction. The study concludes that all NSAIDs, including naproxen, were found to increase an individual's risk and that the risk is greatest during the first month of NSAID use, as well as with higher doses of the drugs.

- **Analysis:** Research continues to show that all traditional NSAIDs, including naproxen, appear to be associated with an increased risk of acute myocardial infarction. Onset of risk occurs in the first week of use and short-term use for 8-30 days at a high daily dose is associated with the greatest harms.

- **Limitations:** None.

- **Research/Policy Recommendations:**
    1. Evaluate the use of NSAIDs among the Medi-Cal population, including by those patients with heart disease or risk factors for developing heart disease.
    2. Continue to monitor research and FDA communications regarding NSAIDs, in order to determine if the risk of any particular NSAID is definitely higher or lower than that of any other particular NSAID.

- **Clinical Recommendations:**
    1. Health care providers should consider weighing the risks and benefits of NSAIDs before instituting treatment, particularly for higher doses.
    2. Health care providers should remain alert for heart-related side effects the entire time that NSAIDs are being taken and counsel their patients to seek medical attention immediately if they experience symptoms such as chest pain, shortness of breath or trouble breathing, weakness in one part or side of their body, or slurred speech.

8. 2015 Immunization Updates: Influenza, HPV, MenB, PVC13, and SB 277 – September 2015

- **Background:** Starting in 2014, the California Medi-Cal Drug Use Review program began consolidating updates in immunization guidelines, products, and/or research into an annual summary. The 2015 summary included influenza, human papillomavirus (HPV), serogroup B meningococcal disease (MenB), and 13-valent pneumococcal conjugate vaccine (PCV13) immunization updates, as well as a summary of California Senate Bill 277 (Pan, 2015).

- **Purpose:** The purpose of this biennial review is to review updates to the ACIP recommendations for influenza, HPV, MenB, and PVC13 vaccines since the original article was published in September 2015, as well as to review the impact of California Senate Bill 277 (SB 277) on immunization rates in California.

- **Data Criteria and Findings:**

    1. *Influenza vaccine:* During both the 2014 – 2015 and 2015 – 2016 influenza seasons, ACIP recommended the use of live attenuated influenza vaccine (LAIV) for healthy children aged two through eight years without contraindications or precautions to the vaccine. Due to low effectiveness in the United States during those seasons, this recommendation was reversed for both the 2016 – 2017 and 2017 – 2018 seasons. However, for the 2018 – 2019 season, quadrivalent LAIV (LAIV4) was again an available option.

        Additional influenza updates specific to California:
        - Influenza activity in California reached very high levels of severity during the 2017 – 2018 influenza season, increasing in early December and peaking in late-December/early-January. This timing was similar to that seen during the 2016 – 2017 influenza season and earlier than the 2012 – 2013 through 2015 – 2016 influenza seasons in the state. In California, influenza A (H3N2) viruses predominated overall, but influenza B viruses predominated from mid-February through May.
        - For the 2017 – 2018 influenza season the cumulative influenza vaccination coverage estimate in California was 40.0% for all persons 6 months of age and older (down from 48.0% in 2016 – 2017), which is below the national average of 41.7%.

- In 2017, influenza and pneumonia remained the 8th most common cause of death in the United States.
- During the 2017 – 2018 influenza season, the California Department of Public Health (CDPH) received 336 reports of influenza-related deaths among persons less than 65 years of age, compared with 83 deaths during the 2014 – 2015 season, 162 deaths during the 2015 – 2016 season, and 119 deaths during the 2016 – 2017 season.

2. *HPV vaccine:* At their October 2016 meeting, ACIP unanimously voted to update recommendations for HPV vaccine. Two doses of HPV vaccine are now recommended for girls and boys ages 9 through 14 years, with dose 2 administered 6 – 12 months after the first dose (5 months minimum interval). Patients age 15 years or older or younger patients with immunocompromising conditions are recommended to complete a 3-dose schedule. In California, HPV vaccination rates have risen steadily each year since the article was published, with current data from 2017 showing 71.9% of California teens 13 – 17 years of age receiving first-dose HPV vaccination (up from 60.5% in 2014) and 53.4% receiving the complete HPV vaccination series (up from 31.1% in 2014).

3. *MenB vaccine:* In April 2016, the FDA approved changes to the dosing and administration of MenB-FHbp to include both a 3-dose series (administered at 0, 1 – 2, and 6 months) and a 2-dose series (administered at 0 and 6 months). At its October 2016 meeting, ACIP recommended the 3-dose series of MenB-FHbp for people at increased risk for meningococcal disease and for use during MenB disease outbreaks and the 2-dose series for healthy adolescents and people who are not at an increased risk for meningococcal disease. Recommendations for MenB-4C remained unchanged (2-dose series, administered at 0 and ≥ 1 month). Of note, while either MenB vaccine can be used as indicated, they are not interchangeable and the same product must be used for all doses in a series.

4. *13-valent pneumococcal conjugate vaccine (PCV13):* There have been no updates to the ACIP recommendations for PVC13 vaccines since the original article was published in September 2015. In 2016, the CDPH published pneumococcal vaccine timing documents for both adults and children.

5. *SB 277*: A recent study published in Pediatrics in November 2018 found that two school years after the implementation of SB277, the proportion of kindergarten students reported to have received all required vaccines increased from 92.8% in 2015 – 2016 to 95.1% in 2017 – 2018, and the rates of personal belief exemptions (PBEs) steadily declined since the 2013 – 2014 school year. However, the rate of medical exemptions in California after the passage of SB277 has increased 250% (from 0.2% in 2015 – 2016 to 0.7% in 2017 – 2018). Counties that had high PBE rates before SB277 also had the largest increases in medical exemptions during the first year of SB277 implementation, leaving portions of California susceptible to vaccine-preventable outbreaks. Potential explanations for this steep increase include underuse of medical exemptions before SB277 (when PBEs could still be obtained) and the willingness of some physicians to write medical exemptions for parents who are vaccine hesitant whose children may lack scientifically justified medical contraindications as defined by the ACIP.

   During 2018, the CDPH also updated their immunization requirements, which become effective on July 1, 2019. At the start of the 2019 – 2020 school year, California students in TK/K-12 will be required to have 1) two (instead of one) doses of chickenpox vaccine at TK/Kindergarten entry, 7th grade advancement, or TK/K-12 admission or transfer and 2) two MMR doses and three Hepatitis B vaccine doses at admission or transfer for most K-12 students. California students enrolled in pre-kindergarten (child care or preschool) will be required to have the chickenpox vaccine at age 15 months and older (rather than age 18 months and older). As children age into requirements, parents have 30 days to submit updated records showing the child has met the requirements. Also starting July 1, 2019, all medical exemptions must include a signed, written statement from a physician (MD or DO) licensed in California that states:
   - The specific nature of the physical condition or medical circumstance of the child for which a licensed physician does not recommend immunization.
   - Each specific required vaccine that is being exempted.
   - Whether the medical exemption is permanent or temporary.
   - If the exemption is temporary, the expiration date (no more than 12 calendar months from the date of signing).

- **Analysis:** Although the number of students receiving all required vaccines in California increased after the implementation of SB277 and the rates of medical

exemptions are still relatively low (0.7%), counties and jurisdictions that had high PBE rates before SB277 also had the largest increases in medical exemptions during the first year of SB277 implementation. Health officers reported substantial frustration over the lack of authority to review medical exemptions and expressed concern over the rise in medical exemptions after the implementation of SB277. Updated requirements for medical exemptions may help provide key stakeholders with more information. If medical exemption rates continue to rise, portions of California will remain susceptible to vaccine-preventable outbreaks.

- **Limitations:** None.

- **Research/Policy Recommendations:**
    1. Continue to follow updates to immunization regulations and legislation in California.
    2. Continue to work with the CDPH on annual summaries of immunization guidelines, products, and/or research to ensure the highest priority information gets promoted through as many channels as possible.
    3. Develop targeted DUR educational outreach to providers and pharmacies, as needed, to promote vaccination according to CDC guidelines.
    4. Closely monitor surveillance reports for vaccine-preventable diseases through the CDPH website.

- **Clinical Recommendations:**
    1. All prescribers and pharmacies should review immunization status and other evidence of immunity to vaccine-preventable diseases for all patients.
    2. All health care providers should routinely encourage annual influenza vaccine for all patients 6 months of age and older.
    3. All health care providers should feel comfortable addressing myths about vaccines and vaccine-preventable diseases.
    4. Improve practice patterns to use every opportunity to recommend HPV vaccines, including initiating the first dose of HPV vaccine with the required Tdap booster for entry into 7th grade in California.
    5. Providers should use the presumptive approach to improve HPV vaccination initiation rates for preteens ages 11-12 years. Research studies have found that announcements normalize HPV vaccination for both providers and parents, making providers more likely to raise the topic and parents more likely to consent to vaccination.

UCSF School of Pharmacy

DUR Publications: Q4 2018

Shal Lynch, PharmD, CGP
Health Sciences Associate Clinical Professor
Department of Clinical Pharmacy

DUR Publications

January 2019

- Alert – New Naloxone Regulations Effective On January 1, 2019

UCSF

Future Recommendations

- Alerts:
  - California Upgrades Immunization Registry to CAIR2
- Bulletins:
  - Latent tuberculosis infection (approved – publishing February 28, 2019)
  - MEDD update (approved – publishing February 28, 2019)
  - Managing pain in population with comorbid mental health conditions
  - Pharmacist furnishing of naloxone
  - Pharmacist furnishing of hormonal contraception
  - Hypertension medication adherence

Board recommendations?

UCSF School of Pharmacy

Prospective DUR Updates: Q4 2018

Amanda R. Fingado, MPH
Senior Epidemiologist/Statistician
Department of Clinical Pharmacy

Prospective DUR Updates – Q4 2018

Topics for Discussion:

- New Generic Code Number (GCN) Alert Profiles
- Therapeutic Duplication (TD) Alert: Update
- Additive Toxicity (AT) Alert: Gabapentinoids

New GCN Alert Profiles

Background

- Each week new Generic Code Numbers (GCNs) are added
- Overutilization (ER), Drug-Pregnancy (PG) and Drug-Drug Interactions (DD) alerts are automatically turned on for all new GCNs
- New GCNs are reviewed weekly for additional alerts
- New GCNs with alerts turned on other than ER, PG, and DD are provided at each Board meeting for review

New GCN Alert Profiles (cont.)

Table 1. New GCNs for Existing DUR Target Drugs: Q4 2018

GCN(s)	Drug Description	Alerts Turned on
078155 - 078160	ARIPIPRAZOLE	MC, TD, LR, AT, ID, HD, LD
078957	CHLORPHENIRAMINE/PE/CODEINE	AT, PA
078661 - 078863	CLOBAZAM	AT
078712, 079289	DIAZEPAM	AT, HD, LD
078815, 078816	ESTRADIOL	MC
079213	ESTRADIOL HEMIHYDRATE	MC
078757	FENTANYL CITRATE/PF	DA, MC, TD, AT, ID, HD, LD
078729 - 078731	HYDROMORPHONE HCL	AT
079369, 079370	LEVOTHYROXINE SODIUM	TD, LR, ID, HD, LD
078733, 078734	LORAZEPAM	AT, HD
078735 - 078737	MEPERIDINE HCL/PF	AT
079083, 079085, and 079887	TESTOSTERONE ENANTHATE	DA, TD, LR, ID, HD, LD

Board questions/recommendations?

TD Alert: Update

- Therapeutic Duplication (TD) alert for lithium is now OFF
  - Ingredient Duplication (ID) alert remains on for all 300 mg formulations
- Ingredient Duplication (ID) alert for quetiapine is now ON
  - Therapeutic Duplication (TD) alert for quetiapine now only generated when there are active paid claims for other antipsychotics

Board questions/recommendations?

AT Alert: Gabapentin

- Gabapentinoids are under consideration for addition to the list of drugs for additive toxicity (AT) alert
  - Based on side effect profile, literature review, and analysis of pharmacy claims data
- Board interest in a retrospective review of gabapentinoids?
  - ICD-10 data
  - Use of concomitant medications

Board questions/recommendations?

UCSF School of Pharmacy

DUR Educational Outreach: Q4 2018

Amanda R. Fingado, MPH
Senior Epidemiologist/Statistician
Department of Clinical Pharmacy

Background: Additive Toxicity (AT) Letter

- FDA requiring changes to drug labeling due to serious risks associated with the use of opioids in combination with benzodiazepines and other CNS depressants
- Medi-Cal DUR program now focusing the additive toxicity (AT) alert on CNS depressants
- In June 2018, a total of 307 Medi-Cal FFS beneficiaries generated AT alerts due to concomitant use of opioids, benzodiazepines, and at least one additional CNS depressant

Objectives: AT Letter

- To identify beneficiaries at high-risk for adverse events associated with the use of certain opioid medications in combination with benzodiazepines and other CNS depressants
- To help inform health care providers and patients of the serious risks attributed to co-prescribing of opioids with CNS depressants, including benzodiazepines, non-benzodiazepine receptor agonists, and antipsychotics

Methods: AT Letter

- Inclusion criteria:
  - Generated an AT alert (with pharmacist override) December 2018
  - Between 10/1/18 and 12/31/18 had at least one paid claim for both an opioid and a benzodiazepine, as well as paid claims for at least two additional CNS depressants
- Exclusion criteria:
  - Practice locations including SNF, ICF, home health, hospice
  - Diagnostic codes indicating palliative care or cancer treatment

Methods: AT Letter (cont.)

- Study population included 31 continuously-eligible Medi-Cal FFS beneficiaries
- Letters included patient profiles, Medi-Cal DUR AT article, naloxone handout, and provider surveys
- Letters mailed to 67 prescribers on January 18, 2019
- Paid claims for gabapentin were also included on profiles

Outcomes: AT Letter

- Primary:
  - Total continuously-eligible beneficiaries without active paid claims for both opioids and benzodiazepines after 6 months following the mailing
- Secondary:
  - Total continuously-eligible beneficiaries with a paid claim for naloxone within the 6 months following the mailing

Board recommendations?

Next Board Meeting

May 2019

- Proposal: LTBI
- Outcomes: MEDD - 2019

Future Topics

DUR Educational Outreach to Pharmacies/Providers

- Over-the-Counter Medications
- QT Prolongation
- Late Refill

Board recommendations?

Global Medi-Cal Drug Utilization Review Board Pharmacy Update

Pauline Chan, R.Ph., MBA

February 26, 2019

Topics

1. Improving Naloxone Access
2. CDC Opioid Guidelines Training Modules
3. 2019 Child Core Set
4. 2019 Adult Core Set
5. CMS All State Drug Utilization Review (DUR) Meeting
6. DUR Annual Report 2018 – Update and Timeline

Improving Naloxone Access - 1

- Naloxone Distribution Project

Improving Naloxone Access - 2

- Naloxone Access Options in California
  - California Health Care Foundation (CHCF)
    - Information organized by stakeholder type and naloxone access options
    - Includes links to overdose prevention and response training, information for prescribers, and for people who use drugs
    - Centralize information in one single sheet document (2 pages)

CDC Opioid Guidelines

- Applying CDC's Guidelines for Prescribing Opioids
  - An online training series (nine modules) to help providers apply CDC's recommendations in clinical settings
  - Each module is stand-alone and self-paced
  - Free CEs
    - Registration: Training and Continuing Education Online (TECO)
- CDC Opioid Prescribing Guideline Mobile Application
  - Includes guidelines, calculators, other resources and more

2019 Child Core Set

- Child Health Care Quality Measures
  - How states report quality measures
  - Reports
- 2019 Child Core Set
  - No new measure added or retired from 2018 core set
  - Tools to monitor and improve the quality of care
  - Measures are reassessed annually
- Aligning DUR goals with adult and child core sets
  - Medication related measures

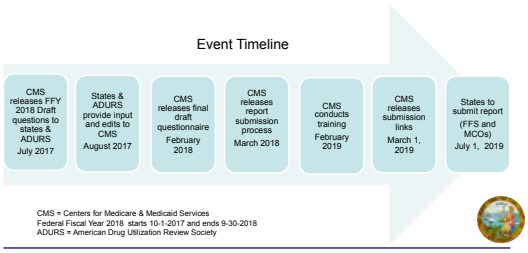
2019 Adult Core Set

- Adult Health Care Quality Measures
- 2019 Adult Core Set
- No new measure added or retired from 2018 core set

CMS All State DUR Meeting

- All State Drug Utilization Review (DUR) Meeting (1/22/19)
  - DUR Annual Review Surveys (FFS and MCO)
  - DUR Minimum Requirements (SUPPORT Act)
- SUPPORT Act
- CMS to provide further guidance in upcoming months

DUR Annual Report FFY 2018 Timeline



DUR Annual Report FFY 2018 DHCS Update

- Each managed care health plan to complete a DUR annual report using the MCO fillable questionnaire (PDF), including attachments
- 2018 report covers the period of October 1, 2017 to September 30, 2018
- Number of health plans with reports: 25
- 2018 report to submit to DHCS by April 1, 2019
- DHCS submits FFS and MCO reports to CMS by July 1, 2019
- Annual Report Resources
  - Annual Report Companion Guide
  - FAQs
  - CMS guidance

Questions?

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

All State Drug Utilization Review (DUR) Meeting

Centers for Medicare and Medicaid Services, Center for Medicaid and CHIP Services

Division of Pharmacy

January 22, 2019

Agenda

1. 2019 Fee For Service (FFS) and Managed Care Organization (MCO) Annual DUR Surveys
2. DUR Minimum Requirements
   a) Opioid Legislation (SUPPORT Act)
   b) Additional SUPPORT Act DUR Minimum Standards
3. Next Steps

2

DUR ANNUAL SURVEYS (FFS and MCO)

3

State Process for 2019 survey

- No more SurveyGizmo!
- States will be able to enter DUR FFS information into new Medicaid Drug Program (MDP) system starting March 1, 2019.
- States will send PDF survey to all state MCOs through MDP:
  - MCOs have to return surveys to state for upload into MDP system
- States are responsible for posting all surveys in MDP – FFS and MCOs by July 1, 2019.
- CMS will post all surveys on Medicaid.gov and will continue to publish annual DUR comparison report.

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MDP System Overview

- Medicaid Drug Rebate and Utilization Review Programs State Agency Contact Form (CMS-368)
  - Updated via Paperwork Reduction Act (PRA) of 1995 to include DUR State Contact

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MDP System Overview

MEDICAID DRUG REBATE PROGRAM (MDRP) and DRUG UTILIZATION REVIEW PROGRAM (DUR) STATE AGENCY CONTACT FORM (excerpt)

DUR STATE CONTACT – Person responsible for state DUR. Person must have a valid state email address.

NAME OF CONTACT EMAIL ADDRESS

TEL: AREA PHONE NUMBER EXT. FAX: AREA PHONE NUMBER EXT.

NAME OF FISCAL AGENT (if applicable)

STREET ADDRESS

CITY STATE ZIP CODE

CMS-368 (Exp. XX/XX/XXXX) / OMB No. 0938-0582 / Rev. 2/2019

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0582. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

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2019 DUR Surveys

- Data FFY 2018
- Medicaid Drug Program (MDP) System
  - The MDP web application uses the same browser versions used by CMS enterprise portal. See https://portal.cms.gov
  - Access (Enterprise Identity Management <EIDM> Portal)
  - State DUR Medicaid Contact
  - State DUR Medicaid Designee
  - Go Live: March 1, 2019
  - Submission Deadline: July 1,2019

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MDP System Overview

How do I get access to MDP?

- Enterprise Identity Management (EIDM), CMS' Enterprise Portal.

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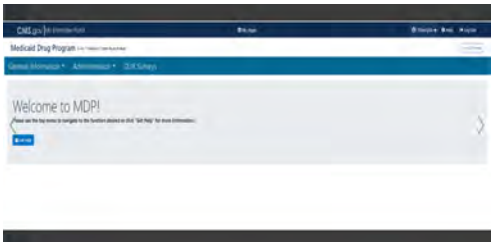
MDP System Overview

Welcome to MDP



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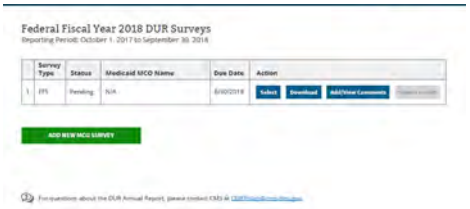
MDP System Overview (DUR FFS)

State DUR Contact View



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MDP System Overview (DUR FFS)

State DUR Contact View

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MDP System Overview (Dashboard)

State DUR Contact View

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2019 FFS DUR Survey

- To be entered directly into the CMS MDP System
- State DUR Contact will respond to survey questions and/or review delegated sections of the survey from State designees, certify, and once entire survey is complete, submit through the CMS MDP System

2019 MCO DUR Survey Issues

- PDF Fillable Survey: One for each MCO
- ADURS Training
- Edits/Adjustments
- MCO Transitions: Contract with State Ends

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2019 MDP DUR Survey Demonstration

- ADURS
  - Annual Meeting February 21-23, 2019 in Scottsdale, AZ
  - DUR Demonstration by our MDP contractor DCCA

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2019 DUR Survey Q&A

- Q&A Document
  - For additional information, contact the CMS DUR Team

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DUR Minimum Requirements (Support Act)

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Opioid Standards and DUR Program

- States need to implement the requirements in H.R. 6, Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities" Act - (Implementation October 2019)
  - Many states already have implemented these standards.
- States need to submit a SPA by December 2019
- CMS will issue a guidance to states regarding requirements that should be included in the SPA
- Guidance will also indicate contract changes that must occur between state and MCOs.
- CMS may issue additional DUR standards through future rulemaking that will require state/MCO compliance.

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Opioid Legislation

Title 1 - Section 1004: Medicaid Drug Review and Utilization (Implementation: CMS/CMCS/Division of Pharmacy)

Requirements:

- ✓ Safety Edits, as specified by the states, for subsequent opioid fills and maximum daily morphine equivalent that exceed state-defined limitations
- ✓ Automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics;
- ✓ Monitoring antipsychotic prescribing for children
- ✓ Process that identifies potential fraud or abuse by enrolled individuals and pharmacies
- ✓ Report to the Secretary annually on state DUR activities
- ✓ Have in place managed care contracts that include these provisions

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New Medicare Part D Opioid Standards

How do new Medicaid requirement compare to new Medicare Part D DUR Opioid Requirements

- Soft edit for concurrent opioid and benzodiazepine use (in H.R. 6)
- Soft edit for duplicative long-acting (LA) opioid therapy (not in H.R. 6)
- Care coordination edit at 90 morphine milligram equivalents (MME) (in H.R. 6)
- Hard edit at 200 MME or more (optional) (in H.R. 6)
- Hard edit 7 day supply limit for initial opioid fills (not in H.R. 6)

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Opioid Legislation (Additional State Requirements)

- **Prescription Drug Monitoring Programs (PDMP)**
  - ***Title 1 - Section 1016. Better data sharing to combat the opioid crisis.*** - This provision clarifies states' ability to access and share data from prescription drug monitoring program databases, consistent with the parameters established in state law, including with providers and managed care entities, and in adherence to applicable security and privacy protections and laws.
  - **Effective Date: Date of Enactment**

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Opioid Legislation (Additional Standards)

- ***Title V - Subtitle E – Section 5042. Medicaid providers are required to note experiences in record systems to help in-need patients.*** - These provisions require Medicaid providers to check relevant PDMPs before prescribing a Schedule II controlled substance. The policy also encourages Medicaid providers to integrate PDMP usage into a Medicaid provider's clinical workflow and establishes standard criteria that a PDMP must meet to be counted as a qualified PDMP. Requirement of state Medicaid programs to report to CMS on PDMP data and information.
- **Effective Date: October 1, 2021**

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Opioid Legislation (Additional Standards)

- ***Title VII - Subtitle Q—Section 7161, 7162. Preventing overdoses of controlled substances; Prescription drug monitoring program.*** - These provisions authorize CDC and SAMSHA support for states and localities to improve their Prescription Drug Monitoring Programs (PDMPs), collect public health data, and implement other evidence-based prevention strategies. It also encourages data sharing between states and supports other prevention and research activities related to controlled substances, including education and awareness efforts.
- **Authorizes the appropriation of $496 million for each of FY2019 through FY2023 to implement Sections 7161 and 7162.**

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Next Steps

- 2019 State FFS/MCO DUR Surveys:
  - States to receive follow up information through the CMS DUR listserve in reference to MDP registration through EIDM
- CMS to issue formal guidance on SUPPORT Act requirements
- States to develop and submit their updated State Plan Amendment to comprise requirements from the Support Act by December 2019
- States to submit comments/recommendations for additional and potential DUR minimum standards

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Resources

- **Medicaid.gov Drug Utilization Review Home Page:** https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/index.html
- **Opioid Legislation** https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf

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Contact Information

CMS DUR Team:
CMSDUR@cms.hhs.gov

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Questions

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MEDICAID MANAGED CARE ORGANIZATION
DRUG UTILIZATION REVIEW ANNUAL REPORT
FEDERAL FISCAL YEAR 2018

42 CFR 438.3(s)(4) and (5) require that each Medicaid managed care organization (MCO) must operate a drug utilization review (DUR) program that complies with the requirements described in Section 1927 (g) of the Social Security Act (the Act) and submit an annual report on the operation of its DUR program activities. Such reports are to include: descriptions of the nature and scope of the prospective and retrospective DUR programs; a summary of the interventions used in retrospective DUR and an assessment of the education program; a description of DUR Board activities; and an assessment of the DUR program's impact on quality of care.

This report covers the period October 1, 2017 to September 30, 2018. Answering the attached questions and returning the requested materials as attachments to the report will constitute compliance with the above-mentioned statutory and regulatory requirements.

If you have any questions regarding the DUR Annual Report, please contact your state's Medicaid Pharmacy Program.

This survey is for viewing purposes only and not for submission. Survey submission will be performed through the CMS Medicaid Drug Program (MDP) System available March 1, 2019. As the surveys are being generated through our MDP System, formatting and question access may differ slightly to the attachment provided.

MEDICAID MANAGED CARE ORGANIZATION
DRUG UTILIZATION REVIEW ANNUAL REPORT
FEDERAL FISCAL YEAR 2018

I. DEMOGRAPHIC INFORMATION

MCO Name: _____

Medicaid MCO Information

Identify your MCO person responsible for DUR Annual Report Preparation.

First Name: _____

Last Name: _____

Email Address: _____

Area Code/Phone Number: _____

1. On average, how many Medicaid beneficiaries are enrolled monthly in your MCO for this Federal Fiscal Year?

   _____ beneficiaries

II. PROSPECTIVE DUR (ProDUR)

1. Indicate the type of your pharmacy point of service (POS) vendor and identify it by name.

   ○ State-operated

   ○ Contractor, please identify by name.

   _____

   ○ Other organization, please identify by name.

   _____

2. Identify prospective DUR criteria source.

- ○ First Data Bank
- ○ Medi-Span
- ○ Other, please specify.

3. Who reviews your new prospective-DUR criteria?

- ○ MCO's DUR Board
- ○ FFS agency DUR Board
- ○ Other, please explain.

4. Are new ProDUR criteria approved by the DUR Board?

- ○ Yes
- ○ No, please explain.

5. When the pharmacist receives a level-one ProDUR alert message that requires a pharmacist's review, does your system allow the pharmacist to override the alert using the "NCPDP drug use evaluation codes" (reason for service, professional service and resolution)?

   - ○ Yes
   - ○ No
   - ○ Partial, please explain.

6. Do you receive and review follow-up periodic reports providing individual pharmacy provider override activity in summary and/or in detail?

   ○ Yes

   ○ No, please explain.

If the answer to question 6 is "No," skip to question 7.

If the answer to question 6 is "Yes," please continue below.

a) How often do you receive reports?

   ○ Monthly

   ○ Quarterly

   ○ Annually

   ○ Other, please explain.

b) Do you follow up with those providers who routinely override with interventions?

- ○ Yes
- ○ No, please explain.

*If the answer to question 6b is "No,"**skip to question 7.***

If the answer to question 6b is "Yes," please continue below.

By what method do you follow up?

- ○ Contact Pharmacy
- ○ Refer to Program Integrity for Review
- ○ Other, please explain.

7. **Early Refill**

a) At what percent threshold do you set your system to edit?

Non-controlled drugs:

_____ %

Schedule II controlled drugs:

_____ %

Schedule III through V controlled drugs:

_____ %

b) **For non-controlled drugs**

When an early refill message occurs, does your MCO require prior authorization?

- ○ Yes
- ○ No

If the answer to question 7b is "Yes," who obtains authorization?

- ○ Pharmacist
- ○ Prescriber
- ○ Either

If the answer to question 7b is "No," can the pharmacist override at the point of service?

- ○ Yes
- ○ No

c) **For controlled drugs**

When an early refill message occurs, does your MCO require prior authorization?

- ○ Yes
- ○ No

If the answer to question 7c is "Yes," who obtains authorization?

- ○ Pharmacist
- ○ Prescriber
- ○ Either

If the answer to question 7c is "No," can the pharmacist override at the point of service?

- ○ Yes
- ○ No

8. When the pharmacist receives an early refill DUR alert message that requires the pharmacist's review, does your MCO's policy allow the pharmacist to override for situations such as:

- ☐ Lost/stolen Rx
- ☐ Vacation
- ☐ Other, please explain.

9. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?

   ○ Yes

   ○ No

   If "Yes," please explain your edits.

   If "No," do you plan to implement this edit?

   ○ Yes

   ○ No

10. Does the MCO have any policy prohibiting the auto-refill process that occurs at the POS (i.e. must obtain beneficiary's consent prior to enrolling in the auto-refill program)?

    ○ Yes

    ○ No

11. Does your MCO have any policy that provides for the synchronization of prescription refills (i.e. if the patient wants and pharmacy provider permits the patient to obtain non-controlled chronic medication refills at the same time, your MCO would allow this to occur to prevent the beneficiary from making multiple trips to the pharmacy within the same month)?

    ○ Yes

    ○ No

12. For drugs not on your MCO's formulary, does your MCO have a documented process (i.e. prior authorization) in place, so that the Medicaid beneficiary or the Medicaid beneficiary's prescriber may access any covered outpatient drug when medically necessary?

- ○ Yes
- ○ No

If "Yes," what is the preauthorization process?

If "No," please explain why there is not a process for the beneficiary to access a covered outpatient drug when it is medically necessary.

13. Please list the requested data in each category in *Table 1 – Top Drug Claims Data Reviewed by the DUR Board* below.

Table 1: Top Drug Claims Data Reviewed by the DUR Board

Column 1 Top 10 Prior Authorization (PA) Requests by Drug Name	**Column 2** Top 10 Prior Authorization (PA) Requests by Drug Class	**Column 3** Top 5 Claim Denial Reasons Other Than Eligibility (i.e. Quantity Limits, Early Refill, PA, Therapeutic Duplications, Age Edits)	**Column 4** Top 10 Drug Names by Amount Paid	**Column 5** % of Total Spent for Drugs by Amount Paid From data in Column 4, determine the % of total drug spend.	**Column 6** Top 10 Drug Names by Claim Count	**Column 7** Drugs by Claim Count % of Total Claims From data in Column 6, determine the % of total claims.
				%		%
				%		%
				%		%
				%		%
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				%		%

III. RETROSPECTIVE DUR (RetroDUR)

1. Does your MCO utilize the same DUR Board as the state Fee-For-Service (FFS) agency or does your MCO have its own DUR Board?

   - ○ Same DUR Board as FFS agency
   - ○ MCO has its own DUR Board
   - ○ Other, please explain.

2. Identify the entity, by name and type, that performed your RetroDUR activities during the time period covered by this report (company, academic institution, other organization, or indicate if your MCO executed its own RetroDUR activities).

3. Who reviews and approves the RetroDUR criteria?

   - ○ State DUR Board
   - ○ MCO DUR Board
   - ○ Other, please explain.

4. Has your MCO included, a year end summary of the Top 10 problem types for which educational interventions were taken?

○ Yes

○ No

Upload Attachment 1- Retrospective DUR Educational Outreach Summary

See attachment naming instructions.

IV. DUR BOARD ACTIVITY

1. Has your MCO included a brief summary of DUR Board activities during the time period covered by this report?

○ Yes

○ No

Summary of DUR Board Activities

The summary should be a brief descriptive report on DUR Board activities during the fiscal year reported.

- Indicate the number of DUR Board meetings held
- List additions/deletions to DUR Board approved criteria
  a) For prospective DUR, list problem type/drug combinations added or deleted
  b) For retrospective DUR, list therapeutic categories added or deleted
- Describe Board policies that establish whether and how results of prospective DUR screening are used to adjust retrospective DUR screens.
- Describe policies that establish whether and how results of retrospective DUR screening are used to adjust prospective DUR screens
- Describe DUR Board involvement in the DUR education program (i.e. newsletters, continuing education, etc.)
- Describe policies adopted to determine mix of patient or provider specific intervention types (i.e. letters, face-to-face visits, increased monitoring).

Upload Attachment 2 - Summary of DUR Board Activities

See attachment naming instructions.

2. Does your MCO have a Medication Therapy Management Program?

- ○ Yes
- ○ No

If the answer to question 2 is "Yes," please continue with questions a) and b) below.

a) Have you performed an analysis of the program's effectiveness?

- ○ Yes, please provide a brief summary of your findings.

- ○ No

b) Is your DUR Board involved with this program?

- ○ Yes
- ○ No

If the answer to question 2 is "No," are you planning to develop and implement a program?

- ○ Yes
- ○ No

V. PHYSICIAN ADMINISTERED DRUGS

The Deficit Reduction Act requires collection of NDC numbers for covered outpatient physician administered drugs. These drugs are paid through the physician and hospital programs. Has your pharmacy system been designed to incorporate this data into your DUR criteria for:

1. ProDUR?

   ○ Yes

   ○ No

   If "No," do you have a plan to include this information in your DUR criteria in the future?

   ○ Yes
   ○ No

2. RetroDUR?

   ○ Yes

   ○ No

   If "No," do you have a plan to include this information in your DUR criteria in the future?

   ○ Yes
   ○ No

VI. GENERIC POLICY AND UTILIZATION DATA

1. Has your MCO included a brief description of policies that may impact generic utilization percentage?

   ○ Yes

   ○ No

   Upload Attachment 3 - Generic Drug Substitution Policies
   See attachment naming instructions.

2. In addition to the requirement that the prescriber write in his own handwriting "Brand Medically Necessary" for a brand name drug to be dispensed in lieu of the generic equivalent, does your MCO have a more restrictive requirement?

   ○ Yes

   ○ No

   If "Yes," check all that apply:

   - ☐ Require that a MedWatch Form be submitted
   - ☐ Require the medical reason(s) for override accompany the prescription
   - ☐ Prior authorization is required
   - ☐ Prescriber must indicate "Brand Medically Necessary" on the prescription
   - ☐ Other, please explain.

Complete Table 2 – Generic Drug Utilization Data using the following Computation Instructions.

Computation Instructions Key

Single Source (S) – Drugs having an FDA New Drug Application (NDA), and there are no generic alternatives available on the market.

Non-Innovator Multiple-Source (N) – Drugs that have an FDA Abbreviated New Drug Application (ANDA), and generic alternatives exist on the market.

Innovator Multiple-Source (I) – Drugs which have an NDA and no longer have patent exclusivity.

Generic Utilization Percentage

To determine the generic utilization percentage of all covered outpatient drugs paid during this reporting period, use the following formula

$$N \div (S + N + I) \times 100 = \text{Generic Utilization Percentage}$$

Table 2: Generic Drug Utilization Data

	Single Source (S) Drugs	**Non-Innovator (N) Drugs**	**Innovator Multi-Source (I) Drugs**
Total Number of Claims			

CMS has developed an extract file from the Medicaid Drug Rebate Program Drug Product Data File identifying each NDC along with sourcing status of each drug: S, N, or I. This file will be made available from CMS to facilitate consistent reporting across states with this data request.

3. Indicate the generic utilization percentage for all covered outpatient drugs paid during this reporting period, using the computation instructions in *Table 2 – Generic Utilization Data*.

Number of Generic Claims: 0

Total Number of Claims: 0

Generic Utilization Percentage: 0.00

VII. FRAUD, WASTE, AND ABUSE DETECTION

A. LOCK-IN or PATIENT REVIEW AND RESTRICTION PROGRAMS

1. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by **beneficiaries**?

   ○ Yes

   ○ No

   If "Yes," what actions does this process initiate? Check all that apply:

   ☐ Deny claims and require prior authorization

   ☐ Refer to Lock-In Program

   ☐ Refer to Program Integrity Unit

   ☐ Other (i.e. SURS, Office of Inspector General), please explain.

2. Do you have a Lock-In program for beneficiaries with potential misuse or abuse of controlled substances?

   ○ Yes

   ○ No

   If the answer to question 2 is "No," skip to question 3.

   If the answer to question 2 is "Yes," please continue.

   a) What criteria does your MCO use to identify candidates for Lock-In? Check all that apply:

      ☐ Number of controlled substances (CS)

      ☐ Different prescribers of CS

      ☐ Multiple pharmacies

      ☐ Number days' supply of CS

      ☐ Exclusivity of short acting opioids

      ☐ Multiple ER visits

      ☐ PDMP data

      ☐ Same FFS state criteria is applied

      ☐ Other, please explain.

b) Do you have the capability to restrict the beneficiary to:

i) prescriber only

- ○ Yes
- ○ No

ii) pharmacy only

- ○ Yes
- ○ No

iii) prescriber and pharmacy only

- ○ Yes
- ○ No

c) What is the usual Lock-In time period?

- ○ 12 months
- ○ 18 months
- ○ 24 months
- ○ Other, please explain.

d) On average, what percentage of your Medicaid MCO population is in Lock-In status annually?

_____ %

3. Do you have a documented process in place that identifies possible fraud or abuse of controlled drugs by **prescribers**?

   ○ Yes

   ○ No

   If "Yes," what actions does this process initiate? Check all that apply:

   - ☐ Deny claims written by this prescriber
   - ☐ Refer to Program Integrity Unit
   - ☐ Refer to the appropriate Medical Board
   - ☐ Other, please explain.

4. Do you have a documented process in place that identifies potential fraud or abuse of controlled drugs by **pharmacy providers**?

   ○ Yes

   ○ No

   If "Yes," what actions does this process initiate? Check all that apply:

   - ☐ Deny claims
   - ☐ Refer to Program Integrity Unit
   - ☐ Refer to Board of Pharmacy
   - ☐ Other, please explain.

5. Do you have a documented process in place that identifies and/or prevents potential fraud or abuse of non-controlled drugs by **beneficiaries**?

   ○ Yes, please explain your program for fraud, waste or abuse of non-controlled substances.

   ○ No

B. PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

1. Do you require prescribers (in your provider agreement with your MCO) to access the PDMP patient history before prescribing controlled substances?

   ○ Yes, please explain how the MCO applies this information to control fraud and abuse.

   ○ No

   ○ No, the state does not have a PDMP

2. Does your MCO have the ability to query the state's PDMP database?

   ○ Yes

   ○ No

   If "Yes," are there barriers that hinder your MCO from fully accessing the PDMP that prevent the program from being utilized the way it was intended to be to curb abuse?

   ○ Yes, please explain the barriers that exist.

   ○ No

3. Does your MCO have access to border states' PDMP information?

   ○ Yes

   ○ No

C. PAIN MANAGEMENT CONTROLS

1. Does your MCO obtain the DEA Active Controlled Substance Registrant's File in order to identify prescribers not authorized to prescribe controlled drugs?

   ○ Yes

   ○ No

   If the answer to question 1 is "No," skip to question 2.

   If the answer to question 1 is "Yes," please continue.

   Do you apply this DEA file to your ProDUR POS edits to prevent unauthorized prescribing?

   ○ Yes

   ○ No

   If "Yes," please explain how information is applied.

   If "No," do you plan to obtain the DEA Active Controlled Substance Registrant's file and apply it to your POS edits?

   ○ Yes

   ○ No

2. Do you apply this DEA file to your RetroDUR reviews?

   ○ Yes, please explain how it is applied.

   ○ No

3. Do you have a measure (i.e. prior authorization, quantity limits) in place to either monitor or manage the prescribing of methadone for pain management?

   ○ Yes

   ○ No, please explain why you do not have a measure in place to either manage or monitor the prescribing of methadone for pain management.

D. OPIOIDS

1. Do you currently have a POS edit in place to limit the quantity dispensed of an initial opioid prescription?

   ○ Yes, for all opioids

   ○ Yes, for some opioids

   ○ No, for all opioids

   If the answer to question 1 is "No," skip to question 2.

   If the answer to question 1 is "Yes, for all opioids" or "Yes, for some opioids," please continue.

   a) Is there more than one quantity limit for the various opioids?

      ○ Yes, please explain.

      ○ No

b) What is your maximum number of days allowed for an initial opioid prescription?

_____ days

c) Does the above initial day limit apply to all opioid prescriptions?

- ○ Yes
- ○ No, please explain.

2. For subsequent prescriptions, do you have POS edits in place to limit the quantity dispensed of short-acting opioids?

   ○ Yes

   ○ No

   If "Yes," what is your maximum days supply per prescription limitation?

   ○ 30 day supply

   ○ 90 day supply

   ○ Other, please explain.

3. Do you currently have POS edits in place to limit the quantity dispensed of long-acting opioids?

   ○ Yes

   ○ No

   If "Yes," what is your maximum days supply per prescription limitation?

   ○ 30 day supply

   ○ 90 day supply

   ○ Other, please explain.

4. Do you have measures other than restricted quantities and days supply in place to either monitor or manage the prescribing of opioids?

   ○ Yes

   ○ No

   If "Yes," please check all that apply:

   - ☐ Pharmacist override
   - ☐ Deny claim and require PA
   - ☐ Intervention letters
   - ☐ Morphine equivalent daily dose (MEDD) program
   - ☐ Step therapy or clinical criteria
   - ☐ Requirement that patient has a pain management contract or Patient-Provider agreement
   - ☐ Requirement that prescriber has an opioid treatment plan for patients
   - ☐ Require documentation of urine drug screening results
   - ☐ Other, please explain what additional opioid prescribing controls are in place.

   If "No," please explain what you do in lieu of the above or why you do not have measures in place to either manage or monitor the prescribing of opioids.

5. Do you currently have edits in place to monitor opioids and benzodiazepines being used concurrently?

   ○ Yes, please explain.

   ○ No

6. Do you perform any RetroDUR activity and/or provider education in regard to beneficiaries with a diagnosis or history of opioid use disorder (OUD) or opioid poisoning diagnosis?

   ○ Yes

   ○ No

   If the answer to question 6 is "Yes," please indicate how often:

   ○ Monthly

   ○ Quarterly

   ○ Semi-Annually

   ○ Annually

   ○ Other, please explain.

   If the answer to question 6 is "No," do you plan on implementing a RetroDUR activity and/or provider education in regard to beneficiaries with a diagnosis or history of OUD or opioid poisoning in the future?

   ○ Yes

   ○ No

7. Does your state Medicaid agency develop and provide prescribers with pain management or opioid prescribing guidelines?

   ○ Yes

   ○ No

   For either "Yes" or "No," please check all that apply:

   ☐ Your MCO refers prescribers to the CDC's Guideline for Prescribing Opioids for Chronic Pain. Please identify the "referred" guidelines.

   ☐ Other guidelines, please identify.

   ☐ No guidelines are offered.

8. Do you have a drug utilization management strategy that supports abuse deterrent opioid use to prevent opioid misuse and abuse (i.e. presence of an abuse deterrent opioid with preferred status on your preferred drug list)?

   ○ Yes, please explain.

   ○ No

E. MORPHINE EQUIVALENT DAILY DOSE (MEDD)

1. Have you set recommended maximum morphine equivalent daily dose measures?

   ○ Yes

   ○ No

   If the answer to question 1 is "Yes," please continue.

   a) What is your maximum morphine equivalent daily dose limit in milligrams?
   _____ mg per day

   b) Please explain (i.e. are you in the process of tapering patients to achieve this limit?).

   If the answer to question 1 is "No," please explain the measure or program you utilize.

2. Do you provide information to your prescribers on how to calculate the morphine equivalent daily dosage or do you provide a calculator developed elsewhere?

   ○ Yes

   ○ No

   If the answer to question 2 is "No," skip to question 3.

   If the answer to question 2 is "Yes," please continue.

   a) Please name the developer of the calculator.

   _____

   b) How is the information disseminated? Check all that apply:

   ☐ Website

   ☐ Provider notice

   ☐ Educational seminar

   ☐ Other, please explain.

3. Do you have an edit in your POS system that alerts the pharmacy provider that the morphine equivalent daily dose prescribed has been exceeded?

   ○ Yes

   ○ No

   If "Yes," do you require prior authorization if the MEDD limit is exceeded?

   ○ Yes

   ○ No

F. BUPRENORPHINE, NALOXONE, BUPRENORPHINE/NALOXONE COMBINATIONS and METHADONE for OPIOID USE DISORDER (OUD)

1. Does your MCO set total mg per day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs?

   ○ Yes

   ○ No

   If "Yes," please specify the total mg/day:

   ○ 12 mg

   ○ 16 mg

   ○ 24 mg

   ○ Other, please explain.

2. What are your limitations on the allowable length of this treatment?

   - ○ 6 months
   - ○ 12 months
   - ○ No limit
   - ○ Other, please explain.

3. Do you require that the maximum mg per day allowable be reduced after a set period of time?

   - ○ Yes
   - ○ No

   If "Yes," please continue.

   a) What is your reduced (maintenance) dosage?

      - ○ 8 mg
      - ○ 12 mg
      - ○ 16 mg
      - ○ Other, please explain.

b) What are your limitations on the allowable length of the reduced dosage treatment?

- ○ 6 months
- ○ 12 months
- ○ No limit
- ○ Other, please explain.

4. Do you have at least one buprenorphine/naloxone combination product available without prior authorization?

- ○ Yes
- ○ No

5. Do you currently have edits in place to monitor opioids being used concurrently with any buprenorphine drug?

- ○ Yes
- ○ No
- ○ Other, please explain.

If "Yes," can the POS pharmacist override the edit?

- ○ Yes
- ○ No

6. Do you have at least one naloxone opioid overdose product available without prior authorization?

   ○ Yes

   ○ No

7. Does your MCO allow pharmacists to dispense naloxone prescribed independently, or by collaborative practice agreements, or standing orders, or other predetermined protocols?

   ○ Yes

   ○ No

8. Does your MCO cover methadone for OUD (i.e. Methadone Treatment Center)?

   ○ Yes

   ○ No

G. ANTIPSYCHOTICS /STIMULANTS

ANTIPSYCHOTICS

1. Do you currently have restrictions in place to limit the quantity of antipsychotics?

   ○ Yes

   ○ No, please explain.

2. Do you have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children?

   ○ Yes

   ○ No

   If "Yes," please continue.

   a) Do you either manage or monitor:

      ○ Only children in foster care

      ○ All children

      ○ Other, please explain.

   b) Do you have edits in place to monitor (check all that apply):

      ☐ Child's Age

      ☐ Dosage

      ☐ Polypharmacy

      ☐ Other

   c) Please briefly explain the specifics of your antipsychotic monitoring program(s).

If you do not have an antipsychotic monitoring program in place, do you plan on implementing a program in the future?

- ○ Yes
- ○ No, please explain why you will not be implementing a program to monitor the appropriate use of antipsychotic drugs in children.

STIMULANTS

3. Do you currently have restrictions in place to limit the quantity of stimulants?
   - ○ Yes
   - ○ No

4. Do you have a documented program in place to either manage or monitor the appropriate use of stimulant drugs in children?
   - ○ Yes
   - ○ No

   If the answer to question 4 is "Yes," please continue.

   a) Do you either manage or monitor:
      - ○ Only children in foster care
      - ○ All children
      - ○ Other, please explain.

b) Do you have edits in place to monitor (check all that apply):

- ☐ Child's Age
- ☐ Dosage
- ☐ Polypharmacy

c) Please briefly explain the specifics of your documented stimulant monitoring program(s).

If the answer to question 4 is "No," that is you do not have a documented stimulant monitoring program in place, do you plan on implementing a program in the future?

- ○ Yes
- ○ No, please explain why you will not be implementing a program to monitor the appropriate use of stimulant drugs in children.

VIII. INNOVATIVE PRACTICES

Innovative Practices

Have you developed any innovative practices during the past year (i.e. Substance Use Disorder, Hepatitis C, Cystic Fibrosis, MEDD, Value Based Purchasing? Please describe in detailed narrative form any innovative practices that you believe have improved the administration of your DUR program, the appropriateness of prescription drug use and/or have helped to control costs (i.e. disease management, academic detailing, automated prior authorizations, continuing education programs).

Upload Attachment 4 - Innovative Practices

(See naming instructions.

IX. E-PRESCRIBING

1. Does your pharmacy system or vendor have a portal to electronically provide patient drug history data and pharmacy coverage limitations to a prescriber prior to prescribing upon inquiry?

   ○ Yes

   ○ No

   If the answer to question *1 is "Yes,"* do you have a methodology to evaluate the effectiveness of providing drug information and medication history prior to prescribing?

   Please explain your evaluation methodology. Describe all development and implementation plans/accomplishments in the area of e-prescribing. Include any evaluation of the effectiveness of this technology (i.e. number of prescribers e-prescribing, percent e-prescriptions to total prescriptions, relative cost savings).

   Upload Attachment 5 - E-Prescribing Activity Summary

   (See naming instructions.)

   If the answer *to question 1 is "No,"* are you planning to develop this capability?

   ○ Yes

   ○ No

2. Does your system use the NCPDP Origin Code that indicates the prescription source?

   ○ Yes

   ○ No

X. EXECUTIVE SUMMARY

Executive Summary

Upload Attachment 6 - Executive Summary

(See naming instructions.)

APPENDIX

INSTRUCTIONS: Nomenclature Format for Attachments

MCO: Please use this standardized format for naming attachments:

ATT#-FFY-State Abbrev-MCO name-Abbreviated Report name (NO SPACES!)

Example for Arizona: (each MCO should insert its 2 letter state code and its first name)

Attachments:

ATT1-20_ _-AZ-Amerigroup-REOS	(RetroDUR Educational Outreach Summary)
ATT2-20_ _-AZ-Amerigroup-SDBA	(Summary of DUR Board Activities)
ATT3-20_ _-AZ-Amerigroup-GDSP	(Generic Drug Substitution Policies)
ATT4-20_ _-AZ-Amerigroup-IPN	(Innovative Practices Narrative)
ATT5-20_ _-AZ-Amerigroup-EAS	(E-Prescribing Activity Summary)
ATT6-20_ _-AZ-Amerigroup-ES	(Executive Summary)

Note: Although MDP does not place restrictions on the file name of the MCO PDF survey file, a suggested naming convention is FFY-State Abbrev-MCO Name (NO SPACES!)

Background: State Medicaid Fee-For-Service (FFS) and Managed Care Organizations (MCOs) will submit their Federal Fiscal Year (FFY) 2019 DUR reports no later than July 1, 2019 for FFY 2018 DUR activities (October 2017-September 2018). For the first time, individual state MCOs will submit their own individual DUR reports to the states.

1. **How will CMS enable state Medicaid FFS programs and Medicaid MCOs to complete the report?**

   CMS is developing a new CMS-hosted platform called the Medicaid Drug Program (MDP) System. This online system houses the DUR report that will be completed directly by the state FFS programs.

   The system is further being designed to allow each state to send each of its MCOs a fillable PDF form. Once an MCO has completed the report, the MCO will return the completed file(s) to the state, and the state will review, certify, and upload the file(s) into the MDP System.

2. **Who can have access to the MDP system?**

   The State Medicaid DUR Contact (a state employee) will have access and responsibility for the DUR report within the MDP System. Additionally, the State Medicaid DUR Contact will be responsible for delegating access to the MDP System and DUR report (or sections of the report) to State Designees. State Designees may include State employees, State intermediary agents or other users the State designates as involved in completing DUR functions.

   Reports between states are not visible to each other. Additionally, State Designee(s) cannot see other assigned designee(s) sections within their state unless assigned by their State DUR Contact.

3. **What are the roles of the State Medicaid DUR Contact in using the DUR application in the MDP system?**

   The State Medicaid DUR Contact is responsible for:
   - Assigning individual sections of the FFS report to State DUR designees to complete and submit back to the State DUR Contact.
   - Reviewing and certifying the FFS report prior to releasing the report to CMS through the MDP System.
   - Sending the MCO report from the MDP system to each of the MCOs in their state and collect the completed MCO (individual) reports (not combined). MCOs have no access to the MDP system.
   - Reviewing and certifying the MCO report for completeness (not accuracy) prior to releasing the report to CMS through the MDP System.

4. **How will the state receive notification that the FFS and MCO reports are available?**

   Unlike previous reports, the state will not automatically receive a report link. With the new MDP System, each State DUR Contact will need to request and be granted access to the system for notification. Instructions for obtaining user access is being established and will be distributed to State DUR Contacts in advance of implementation (currently, the time frame for the user registration process for the MDP System is pending).

5. **How will the annual report be submitted to CMS? Will a state with multiple MCOs be required to submit responses via email in a single report inclusive of FFS and MCO findings**

   The state will enter the responses to the annual FFS DUR report directly into MDP. For MCO's, the state will coordinate distributing the fillable PDF Annual DUR Report to each of their MCO's to complete. The State DUR Contact will verify completion (not accuracy) by the MCO, then upload the file(s) into the MDP System.

6. **Will CMS provide the state Medicaid program with a listing of specific DUR report questions to be answered by MCOs?**

   Yes. The states will be provided the questions pertinent to the MCOs. CMS provided the American Drug Utilization Review Society (ADURS) a draft of the FFS and MCO questions, and took their comments into consideration in developing the current version of the reports.

7. **How will the FFS and MCO data be presented in roll up reports?**

   For each state, we plan to upload the state's respective FFS report and individual MCO reports. We will likely continue to compile the FFS comparison report. Discussion is continuing to determine how best to summarize and present the MCO DUR reports.

8. **What is the timeline in 2019 for reporting the state's FFS and MCO reports?**

   Submission deadline for both the FFS and MCO Reports is July 1, 2019.

9. **All reports starting NOW will be completed through a log-on access into CMS with credentialing?**

   The reports due July 1, 2019 will include FFS and MCO. The FFS section will be entered directly into the MDP System. The MCOs will complete their report using a fillable PDF form (sent by the State DUR Contact). Once the MCOs complete

their reports, they will return them to the State DUR Contact to review and certify prior to upload into the MDP System.

10. Next year, will states control and coordinate log-on access for their MCO's?

MCOs will not have access to the new MDP System. Log-on access is limited to states only.

11. Please clarify the state's role when certifying MCO data beginning FFY 2019.

State DUR Contacts are expected to review each MCOs report to ensure the report is completed prior to submission. The State DUR Contact will "certify" the MCO report for completeness (not accuracy) prior to submitting to CMS then upload the report to the MDP System.

12. Do states need to upload separate reports for their respective MCOs?

Yes, states will need to upload a completed MCO report for each MCO. The states should work with their MCOs to ensure completed reports are uploaded well before the July 1, 2019 deadline.

13. Is the state or CMS responsible for ensuring MCOs submit DUR reports?

The managed care regulations at §438.3(s) (5) require MCOs to report its DUR activities to the state annually. States are responsible for monitoring their contracted MCO DUR reporting activities, including the completion and submission of the DUR annual report.

14. Are states able to make minor edits or adjustments to received PDF reports on behalf of their MCOs?

No. We do not want the integrity of MCO data reporting to be compromised. Notwithstanding, it is the responsibility of the state to ensure the completeness of the data and responses submitted by the MCOs.

15. How should MCO data collection errors or incomplete reports be addressed?

CMS encourages fiscal intermediaries and/or other state resources to address questions pertaining to incomplete reports or questionable data. Should the fiscal intermediaries and/or other state resources require technical assistance due to complications with report submission, the DUR team is available to assist with that service.

16. **How should states proceed with having their MCOs complete and provide their survey and associated data if an MCO transitions to or from a state during the FFY?**

    States are responsible for assuring their MCOs complete and submit the annual DUR survey. MCOs are required to provide responses to the report questions, and indicate any data limitations where applicable. If an MCO, during the fiscal year of the survey is on contract by your state for 6 months or more, your state is responsible for oversight of that MCO with their survey submission.

17. **What are the minimum software requirements needed to use the new MDP DUR application?**

    a. Fee-For-Service – uses the following browsers for the online report:
        a. Google Chrome – Version 63.0.3239.132 (Official Build) (64-bit)
        b. Internet Explorer – 11 (native browser mode)
        c. Mozilla Firefox – Version 47 (47.0.2)

    b. Managed Care (MCO) – will use Adobe Reader for the PDF report.
        a. Adobe Acrobat Reader DC 2015 or later

    Note: The MDP web application uses the same browser versions used by CMS enterprise portal. See https://portaldev.cms.gov/wps/portal/unauthportal/help/